The Medical Technology Forum

PUBLIC POLICY IMPLICATIONS RELATED TO USE OF THE AIR-FLOTATION BED TREATMENT IN THE HOME SETTING

The Medical Technology and Practice Patterns Institute

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PUBLIC POLICY IMPLICATIONS RELATED TO USE OF THE AIR-FLOTATION BED TREATMENT IN THE HOME SETTING

A Workshop on December 12 - 13, 1988

Sponsored by:
The Medical Technology and Practice Patterns Institute, Inc.
The Medical Technology Forum

and

The Department of Health Care Services
George Washington University Medical Center

And in Cooperation with:
American College of Physicians
American Hospital Association
American Nurses Association
Association of Rehabilitation Nurses
International Association for Enterostomal Therapy
National Association of Home Care
National Center of Nursing Research, NIH
National Institute of Arthritis, and Musculoskeletal and Skin Diseases, NIH
National Pressure Ulcer Advisory Panel
Rehabilitation Nursing Foundation
Visiting Nurses Association

Published by:
MTPPI Press
Medical Technology and Practice Patterns Institute, Inc.
2233 Wisconsin Avenue, N.W., Suite 302
Washington, D.C. 20007

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Printed in the United States of America
Workshop Summary Report

"Public Policy Implications Related To Use Of The Air-Flotation Bed Treatment in the Home Setting"

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A Workshop

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and Skin Diseases, NIH
National Pressure Ulcer Advisory Panel
Rehabilitation Nursing Foundation
Visiting Nurses Association
Workshop Agenda for "Public Policy Implications Related to Air-Flotation Bed Treatment in the Home Setting"
December 12th and 13th, 1988
Capitol Holiday Inn, Washington, D.C.

Monday, December 12th

8:00 a.m.  
Welcome and Workshop Objectives  
Dennis J. Cotter, MSE

Clinical Presentations:

8:05 a.m.  
Overview and Clinical Definitions  
Problem Definition of Pressure Sores  
Glenda Motta, RN ET, MPH

8:20 a.m.  
Physiology of Pressure Sores  
G. Allen Holloway, Jr., M.D.

8:45 a.m.  
Macro Costs of the Management of Pressure Sores  
Jane Kruger, RN

9:00 a.m.  
Financial Impact on Medicare Program  
Flora Chu, M.D.

9:10 a.m.  
Discussion

9:25 a.m.  
Clinical Experience with Air-Flotation Bed Technology - Part I  
Richard M. Allman, M.D.

9:40 a.m.  
Clinical Experience with Air-Flotation Bed Technology - Part II  
Roseann B. Myers, RN, CETM

9:55 a.m.  
Discussion

10:25 a.m.  
Panel Discussion on Patient Management Concerns for the Home Use of Beds  
Marie Brown RN, ET  
Janet La Mantia, MA, RN, CRRN  
Ruby VanCroft, RN

11:00 a.m.  
Discussion

11:10 a.m.  
Panel Discussion on Appropriateness of Proposed Patient Selection Criteria  
Richard M. Allman, M.D.  
Sr. Josephine Bryan, RN, MSN  
Glenda Motta, RN ET, MPH  
Roseann B. Myers, RN, CETM  
Judy A. Wells, RN, BSN, CETN

11:50 a.m.  
General Discussion Period

1:30 p.m.  
Panel Discussion on Future Research Issues  
Katherine Jeter, Ed.D., ET  
G. Allen Holloway, Jr., M.D.
2:10 p.m.  Discussion
Policy Presentations:

2:30 p.m.  Review of Current FDA Regulatory Status and Review of Regulatory Process for Coverage and Reimbursement
Frank Case, J.D.
Ruth E. Galten, RN
Joel E. Miller

3:00 p.m.  Discussion

3:15 p.m.  Panel Discussion on Current Documentation Practices for Pressure Sore Classification
Helen Cioschi, CRNP, MSN, CRRN
Katherine Jeter, Ed.D., ET
JoAnn Maklebust, MSN, RN, CS
Janet La Mantia, MA, RN, CRRN

3:45 p.m.  Discussion

4:00 p.m.  Panel Discussion of Current Clinical Decision Making and Referral Practices for Air-Flotation Bed Treatment
Richard M. Allman, M.D.
Carol Goodman, RN
G. Allen Holloway, M.D.
Holly Lidowski, RN, MSN
Sue Schindler, RN, CETN

4:50 p.m.  Discussion Period and Wrap-Up

Second Day, Tuesday, December 13th, 1988

8:15 a.m.  Summary of First Day’s Discussions and Patient Selection Criteria
Mary Gambosh, RN
Virginia Saba, Ed.D.

9:00 a.m.  General Discussion Period

9:30 a.m.  U.S. Congress’ Bipartisan Commission on Comprehensive Health Care
Robert Burke, Ph.D.

9:45 a.m.  Open Panel Discussion with audience participation

10:30 a.m.  Report of Preliminary Panel Recommendations and Audience Commentary
Panel Members:
Blaine Fitzgerald, M.D.
Mary Gambosh, RN
Stephen J. Jay, M.D., Chairman
Jack Kleh, M.D.
Virginia Saba, Ed.D.
John P. Swope, M.D.
Workshop Speakers and Panel Presenters

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University of Alabama, Birmingham
Birmingham, Alabama

Marie Brown, RN ET
Etris Associates
Philadelphia, Pennsylvania

Sister Josephine Bryan, RN, MSN
Providence Hospital
Washington, D.C.

Robert Burke, Ph.D.
U.S. Congress Bipartisan Commission on Comprehensive Health Care
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Piedmont Hospital
Atlanta, Georgia
Workshop Panel Members

Chairman:

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Methodist Hospital of Indiana, Inc.
Indianapolis, Indiana

Blaine Fitzgerald, M.D.
Private Practice
Bethesda, Maryland

Mary Gambosh, RN, CIRS
VPS Case Management Services
Glen Allen, Virginia

Jack Kleh, M.D.
Blue Cross/Blue Shield National Capitol Plan
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Virginia Saba, RN, Ed.D.
Georgetown University School of Nursing
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Acknowledgments

The Medical Technology and Practice Patterns Institute, Inc. would like to acknowledge with gratitude the assistance and support of the many organizations and individuals who contributed so much to the success of the workshop, "Public Policy Implications Related to Use of the Air-Flotation Bed Treatment in the Home Setting."

First, the Institute greatly appreciates the planning assistance and support of the co-sponsor of the workshop: The Department of Health Care Services, The George Washington University Medical Center. The Institute also wishes to acknowledge the assistance and cooperation of the following organizations: American College of Physicians, American Hospital Association, American Nurses Association, Association of Rehabilitation Nurses, International Association for Enterostomal Therapy, National Association of Home Care, National Center of Nursing Research, National Institute of Arthritis, and Musculoskeletal and Skin Diseases, National Pressure Ulcer Advisory Panel, Rehabilitation Nursing Foundation and the Visiting Nurses Association.

The Institute also appreciates the financial sponsorship provided by the following organizations: American Nurses Association, Association of Rehabilitation Nurses, Bio Clinic Corporation, Gaymer Industries, International Association for Enterostomal Therapy, Kinetic Concepts Inc., National Association for Home Care, Providence Hospital, and Rehabilitation Nursing Foundation.

Second, the Institute is very grateful to the members of the workshop panel. These panel members contributed significantly to the achievement of the objectives for the workshop. The panel, including professionals from the sectors of academic and clinical medicine, community practice, research and third-party payers, expended considerable time, expertise and counsel in formulating the workshop summary findings. The panel members were as follows: Chairman: Stephen J. Jay, M.D., Methodist Hospital of Indiana, Inc., Blaine Fitzgerald, M.D., Bethesda, Maryland, Mary Gambosh, VPS Case Management Services, Jack Kleh, M.D., Blue Cross and Blue Shield National Capitol Plan, Virginia Saba, RN, Ed.D., Georgetown University School of Nursing, and John P. Swope, M.D., George Washington University Medical Center.

Third, the Institute also wishes to give special recognition to the dedicated efforts and foresight of the planning committee, who provided the ideas and fundamental discussions which were necessary for the realization of the original workshop concept. The planning members were as follows: Susan Currence, RN ET, International Association for Enterostomal Therapy (IAET); George Coulbourne, RN, Providence Hospital and American Hospital Association; Ruth Galten, RN, National Association of Home Care; Dorothy Goodman, RN ET, Visiting Nurses’ Association and IAET; Stephen P. Heyse, M.D., National Institute for Arthritis, Musculoskeletal and Skin Diseases, National Institutes of Health; Stanley Katz, Bureau of Eligibility, Reimbursement and Coverage, Health Care Financing Administration; Janet Lamantia, MA, RN, CRRN, Rehabilitation Nursing Foundation; Glenda Motta, RN ET, MPH, International Association for Enterostomal Therapy; Roseann B. Myers, RN ET, American Nurses’ Association and Etris Associates; and Elizabeth L. Riegel, Center for Devices and Radiological Health, Food and Drug Administration.

The Institute also wishes to give especial acknowledgment to the workshop rapporteur, Dr. Katherine Brenneman, Geriatric fellow, Georgetown University Medical Center, and Dr. Flora Chu for all their skills and efforts in writing the summary of the workshop’s proceedings. Also, the Institute takes pleasure in acknowledging members of the staff who worked tirelessly to plan and to organize the workshop’s events: Mary Anne Hamilton, J.D. and William Heath.
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Foreword

This report summarizes the presentations, discussions and findings of the workshop, "Public Policy Implications Related to Use of the Air-Flotation Bed Treatment in the Home Setting." Specific references for articles and other sources of information may be obtained by writing the Medical Technology and Practice Patterns Institute, Inc. (MTPPI), 2233 Wisconsin Avenue, N.W., Suite 302, Washington, D.C. 20007.
I. Prevention of Pressure Ulcers and Early Intervention

A. Pressure ulcers are a significant yet often preventable public health problem. Estimates of the prevalence of pressure ulcers range between 3.5 to 5 million persons in the United States, and reported rates of incidence in the hospitalized population range between 1 to 3%. It was stressed repeatedly in the workshop that the best "cure" is prevention, in terms of economics and quality of care. The costs and benefits associated with prevention and early intervention in the management of pressure ulcers require further definition.

II. Problem Definition of Pressure Ulcers

A. There was agreement that "pressure ulcer" or "pressure sore" is the common terminology in use. The term, pressure ulcer, describes the current state of knowledge of the underlying pathophysiology of pressure as a primary factor. The term "decubitus" is not an accurate description. This is because it has the meaning of "lying down," and ulcers can develop while the patient is in nonrecumbent positions.

The term, "air-flotation bed treatment," was used to refer to both air-fluidized beds (also called bead beds) and to low air-loss beds (also called air sac beds). These beds are designed to decrease the skin surface pressure of the recumbent patient when compared to the skin surface pressure of a patient using a standard hospital bed, and to avoid a decrease in localized blood flow and to promote wound healing.

B. The problem of underreporting of pressure ulcers in third-party claims data was mentioned several times. If this is true, then the incidence and prevalence of their occurrence are underestimated. For example, Richard M. Allman, M.D., cited data from the Johns Hopkins Hospital which showed that only about one third of patients with pressure ulcers were identified with this specific ICD-9-CM code (707). This finding may not be representative of the average community hospital, but further study and documentation of underreporting of pressure ulcers is warranted. In most cases, pressure ulcers are not the primary reason for hospitalization, and other patient comorbidities are regarded as more important. Problems in the adequacy of current coding schemes, biases against and disincentives to identifying pressure ulcer cases because of potential linkages to quality assurance program screens were also cited as contributing factors to underreporting of pressure ulcers.

C. Estimates of the extent of this condition, and its associated morbidity and mortality varied. Data collection on the prevalence and incidence of this condition should be improved.

III. Pathophysiology of Pressure Ulcers

A. The pathophysiology of pressure ulcers is complex. The body of evidence supports the involvement of four major extrinsic factors: pressure, shearing forces, moisture and friction. Other research has included the study of the role of plasminogen, fibrinolytic systems, transcutaneous oxygen tension, cutaneous blood flow and skin temperature. In order to expand this body of knowledge, recommendations for more study of local factors affecting tissue tolerance were given. Additional research on the systemic parameters relating to the etiology and injury processes of pressure ulcers was recommended.

IV. Financial Impact of Pressure Ulcers

A. Given the reported incidence of pressure ulcers, the treatment of pressure ulcers is costly and resource-intensive. In the Medicare prospective payment scheme, there is a low reimbursement rate compared to other
conditions. Also, the denials of some third-party payments for care were reported. This can create disincentives and incentives which influence the practice of medicine or the coding and/or classification of pressure ulcer cases. Reimbursement methods should recognize the costs of care for early intervention. Ideally, a third-party payment rate should recognize the unique costs and resources associated with pressure ulcer management.

V. Patient Risk Factor Assessment

A. The prevailing perception given by experts at the meeting was that impaired nutritional status of the patient is a significant risk factor for development of pressure ulcers. This correlation intuitively makes good sense, however, larger and more rigorous scientific studies to produce additional data on the role of nutrition in the pathogenesis and treatment of pressure ulcers were recommended.

B. Several additional risk factors for development of pressure ulcers were cited. In one study (Allman, R.M. et al, *Annals of Internal Medicine*, Volume 105:337-342, 1986), fecal incontinence, and fractures were cited as being statistically significant factors, along with hypoalbuminemia. Further clarification of the most important factors to identify patients at greatest risk was proposed.

VI. Clinical Experience with Air-Flotation Bed Technology

A. There was no evidence presented at the meeting which indicated significant risks with the use of this technology. In Dr. Allman’s randomized trial of air-fluidized beds vs. conventional therapy in 65 patients, no significant increase in adverse effects was noted (Allman, R.M. et al, *Annals of Internal Medicine*, 107:641-648, 1987).

B. The management of patients in "step-down" care from air-flotation beds, or the decrease of dependency on such beds as well as the management of patients in "step-up" care to air-flotation beds were cited as important clinical concerns. The decision-making considerations and timing for when to move a patient to and from air-flotation bed technology in the continuity of wound care should be further defined.

C. Studies of nursing resource intensity were described as ongoing; more definitive data are needed. Furthermore, these studies should have a more standardized approach or at least be able to have some cross-correlation.

VII. Patient Management Concerns for the Home Use of Beds

A. A significant component of home therapy for pressure ulcers was cited as patient education, and cooperation and training of the caregiver. This education and understanding is an important need to assure success. Continued monitoring of the appropriateness of use of these beds in the home setting was also cited as important.

B. There are also important educational implications for the health care professions. Heightened awareness should be given in health care professional education to the use of such technology in the home setting and other alternative settings of care.

C. Resource requirements could be substantial in order to place an air-flotation bed into the patient’s home. For example, the significant electrical power needs and floor loading requirements, door size and room entry needs for the air-fluidized bed treatment were described. Given a determination that this treatment is appropriate care, existing local and/or regional government authorities should ensure that the appropriate safety codes and requirements are met.

D. Unlike some other medical technologies approved for home use, the air-flotation bed technology was thought not to pose significant safety risks to the patient or family in case of an equipment malfunction.
VIII. Patient Selection Criteria

A. It was emphasized that patient selection criteria should be applicable to the individual patient, and that a single or rigid formula would not describe all patients appropriately benefiting from such care. Instead, it was suggested that the eligibility criteria be based on a more flexible grouping of patient characteristics. The clinical basis for the selection of important patient characteristics appears to have been formed. The community of providers of air-flotation bed treatment is actively working to refine criteria for patient selection.

B. The ethical issues of patient selection for this specialized and costly technology were raised. Concerns for the fairness and equity of patient selection were discussed. The goal of appropriate treatment for the individual patient should be the primary objective, which include quality-of-care objectives to promote or maintain patient comfort as well as to relieve pressure and to reduce pain.

IX. Future Research Issues

A. A number of research funding issues were raised. One concern was over the availability, the amount of and the ease of obtaining research funds from public and private sources. It was noted that there were limited budgets, rigorous processes for eligibility, and difficulties in funding demonstration projects from the federal government agencies. The problem of pressure ulcers is a significant public health problem in the elderly population and other high-risk groups, i.e., patients suffering from paralysis and degenerative neuromuscular diseases. Therefore, related research topics are in the scope and interest of the Health Care Financing Administration for funding purposes, as well as of other federal agencies with special interests in the immobile patient population.

B. Topics for additional research and study included skin and soft tissue physiology, prevention of pressure ulcers, the role of nutrition, the pathophysiology of pressure ulcers, endpoints of treatment, comparative benefits of different surfaces used to treat pressure ulcers, objective measures of injury and healing, the contributions of pressure ulcers to mortality and morbidity, the development of clinical decision support systems, risk assessment instruments and the performance of cost-effectiveness and cost-benefit analyses.

C. G. Allen Holloway, M.D., described newer research techniques such as measurements of cutaneous blood flow using a laser Doppler technique and nuclear magnetic resonance spectroscopy to characterize tissue changes that precede the development of pressure ulcers.

X. Current Documentation Practices for Pressure Ulcer Classification

A. Differences in the classification of pressure ulcers among providers and payors of care in various institutional settings were identified. Difficulties in arriving at a consensus upon and application of a national standard classification scheme in these circumstances were cited. Third-party payers require a readily understandable and precise classification scheme, but researchers and clinicians have needs for a more complex and detailed system of description. It was suggested that a schema which incorporated general pressure ulcer categories with more specific subgroups of pressure ulcer descriptions could help to satisfy the purposes of both reimbursement and research. The salvage of existing data bases by correlating descriptions to a new or uniform classification scheme was also emphasized.

XI. Current Clinical Decision Making Processes

A. There already appears to be a basis for the private sector to evolve consensus standards of care and outcome assessment tools. Existing documents in use in the public and private sectors could be carefully reviewed for this purpose. This consensus should be a product of the existing peer review processes in the professional societies whose members are involved in the care of these patients.
PANEL FINDINGS AND RECOMMENDATIONS:

I. What are the available specialized types of bed therapy which are used to treat pressure ulcers?

The specialized types of bed therapy discussed in the workshop included air-fluidized beds, also known as bead beds, and low air-loss beds, also known as air-sac beds. These two technologies have been grouped together by caregivers into the general category of air flotation bed treatment.

II. What are the therapeutic equivalences and differences between these two types of technologies?

During the workshop, the panel heard no evidence that would further differentiate air-fluidized beds from low air-loss beds in terms of therapeutic intent. Both these technologies have been used and continue to be used for pressure relief in the treatment of pressure ulcers. Therefore, the panel would recommend expanding the current Public Health Service Office of Health Technology Assessment’s evaluation of air-fluidized bed therapy to include low air-loss bed therapy.

III. What is the evidentiary basis for their safety and effectiveness?

At the workshop, evidence on the use of air-floating bed treatment was presented from the speakers and panelists, based on expert opinion, group consensus, and clinical practice experience. Dr. Allman described one randomized controlled clinical trial of 65 patients, comparing air-fluidized beds and conventional therapy for pressure ulcers. He also cited a study of preventive devices for pressure ulcers.
performed by Andersen et al (Acta Dermatologica, Volume 62:227, 1982). (However, this cited study does not study bed technology which is comparable to technologies currently available in the United States). There were no comparative studies of different air-flotation bed technologies, or of the comparison of the safety and effectiveness of air-flotation bed therapies and pressure-reduction therapies presented at the workshop.

IV. What are the patient management and technical concerns which need to be considered in the home setting?

Important patient management and technical concerns included patient education, cooperation and understanding, family, or home caregiver education, cooperation and training, clinical evaluation, supervision and monitoring of care, specialized training of the health care professional, and equipment maintenance and support.

V. For which types of patients are these specialized technologies medically necessary?

The use of air-flotation bed treatment could be considered medically necessary in cases meeting all the following conditions:

- Presence of an existing medical condition (e.g., a pressure ulcer) which clinically warrants the use of air-flotation bed technology
- Ineffectiveness or failure of other available treatments
- Demonstration of the efficacy of air-flotation bed treatment, and
- Absence of co-existing factors or complications which contraindicate home treatment

VI. What are the important directions for future research?

In order to advance established medical practices, future directions should include studies in the fields of basic, clinical and applied research and development, and health services research which build upon the existing foundations of knowledge and research related to air-flotation bed treatment. These studies would include basic research on the pathophysiology and pathogenesis of pressure ulcers, applied research in clinical care methods, comparative studies of pressure-relief technologies, development of a relational database of utilization of services for the treatment of pressure ulcers and other clinically warranted conditions, health services research of innovative reimbursement strategies, demonstration projects, and evaluation of the significance and validation of regional variations in care and hospitalizations as found in the National Hospital Discharge Survey. Also, opportunities for creating new funding mechanisms or providing for research and demonstration funds from existing public and private sources are recommended. Some or all of these items may also be appropriate for consideration by the National Pressure Ulcer Advisory Panel or other medical specialty groups such as the International Association for Enterostomal Therapy for their research activities.
PART II. INTRODUCTION AND WORKSHOP OBJECTIVES

INTRODUCTION

The introduction of air-flotation bed treatment, which includes both air-fluidized beds and low air-loss beds, has provided pressure relief and facilitated resolution of ulcers for hospitalized patients. The changing forces of health care delivery, including the shift of services from the inpatient setting to the outpatient side, which has been driven not only by technological changes and adaptations but also by patient preferences for comfort and convenience, and the imperative to save on costly hospitalizations have made it now possible to consider the application of such technologies in the home setting. In some areas of the country, these bed treatments are being applied in the home in order to treat the condition of pressure ulcers and to reduce the need for hospitalization.

At this time, there is no national Medicare coverage determination regarding the use of low air-loss beds in the home setting. In the absence of a national policy determination regarding the approval or denial of coverage, it is left up to each local intermediary or carrier to decide whether to cover these services in the home setting, or to decide on a case-by-case basis. Air-fluidized beds are not covered in the home setting according to Medicare policy. Currently, the Health Care Financing Administration is evaluating its coverage policy position towards the use of air-fluidized bed therapy in the home. The Public Health Service's Office of Health Technology Assessment began its assessment of this technology, its appropriate uses and proposed patient selection criteria in 1987.

WORKSHOP OBJECTIVES

This workshop was initiated in order to address important policy-related questions raised about the appropriate use of air-flotation bed technology to treat pressure ulcers. This forum convened primary care providers, researchers, academicians, private third-party payers, patient representatives and government regulators and decision makers to collaborate and to assess the clinical applications of these technologies in a systematic and open manner. This workshop was designed to provide opportunities for scientific review among colleagues, the discussion of significance and implications for public policy, and the formulation of recommendations for the improvement of patient care. The application of pressure-reducing devices such as air or water mattresses, lambs wool and other devices to prevent and treat pressure ulcers was not in the purview of the workshop objectives, although this category of devices is acknowledged as a very important component of the continuum of wound care and worthy of attention.

Recognized experts in the field were selected to present scientific evidence, and panels made up of clinicians, public representatives and academicians were chosen to address concerns in a comprehensive fashion. General discussion periods were allotted so that other individuals and groups could raise questions or state their opinions. Questioning, exchange and debate were encouraged among the presenters, speakers and audience.

PANEL PROCESS

A workshop panel was drawn from specialists and generalists from the medical and nursing professions, academicians, and representatives of third-party payers. After all points of view and evidence were presented, the panel considered and weighed the evidence, and developed a set of responses to specific issues. The panel recommendations were intended to help improve policies which govern the accessibility to and appropriate use of these technologies in order to enhance the quality of life for patients with pressure ulcers.

The key steps in these workshop deliberations to help formulate the basis for the subsequent panel discussions were outlined as follows, which were based on Dr. David Eddy's "Steps to the Formulation of the Problem to be
Addressed by Practice Guidelines:
1) Definition of the clinical problem and its characteristics; 2) Definition of the intervention and its therapeutic intent; 3) Identification of the desirable health outcomes; 4) Description of patient characteristics which are indications or contraindications to treatment; and 5) Identification of setting characteristics which influence health outcomes or selection of treatment modality.

The rules governing the panel process in this workshop were as follows. An independent, diverse expert panel was assembled for bringing a balanced, broad-based and thoughtful attentiveness to the subject at hand. The panel was charged with responding to a number of specific questions, which were circulated to all participants at the workshop. The panel met with the general audience and participants for the presentations of all data, findings, informal discussions, and question and answer sessions. In additional executive sessions, the panel met to discuss the workshop proceedings and to prepare their workshop statement. At the end of the meeting, the draft statement of findings and recommendations were presented in plenary session and were subject to thorough review and open discussion. Following the public discussion, and the consideration of all commentary, the panel reviewed and modified the document as necessary. This draft document was then circulated among the workshop speakers and participants for further review and commentary prior to finalization. After approval of this final, thoroughly reviewed document, this statement now stands as the official record of the workshop panel. The final objective is to promote communication and dissemination of this statement, so that its impact on health care practice and public policy is enhanced.

The specific questions related to air-flotation bed technology and the formulation of public policies were set forth as follows:

- What are the available specialized types of bed therapy which are used to treat pressure ulcers?
- What are the therapeutic equivalences and differences between these two major types of technologies?
- What is the evidentiary basis, i.e., expert opinion, consensus, clinical practice, clinical trials, etc., for their safety and effectiveness?
- What are the important patient management and technical concerns which need to be considered in the home setting?
- For which types of patients are these specialized technologies medically necessary in the home setting?
- What are the important directives for future research?

In order to address these questions, the Medical Technology and Practice Patterns Institute, Inc. and the Department of Health Care Services of the George Washington University Medical Center convened the workshop on the "Public Policy Implications Related to Air-Flotation Bed Treatment in the Home Setting" on December 12th and 13th, 1988, in Washington, D.C. The workshop was also held in cooperation with and assisted by the following organizations: American College of Physicians, American Hospital Association, American Nurses Association, Association of Rehabilitation Nurses, International Association for Enterostomal Therapy, National Association of Home Care, National Center of Nursing Research, National Institute of Arthritis, and Musculoskeletal and Skin Diseases, National Pressure Ulcer Advisory Panel, Rehabilitation Nursing Foundation and the Visiting Nurses Association.

BACKGROUND

Pressure ulcers pose a common clinical problem. The impact of this problem on patient rehabilitation, health care resources, and costs of management is significant. The problem becomes more complicated when considering the growing numbers of the elderly population, gains
in survival of patients with chronic diseases and disabilities, the requirements for extended care facilities, the shift of services and patient preferences for other settings of care such as the home, and the budgetary realities of health care cost containment. In this changing environment, providers of care and policy makers must come together to make decisions about how best to care for these patients, and to minimize or alleviate their disability, pain and associated morbidity. A review of the definition of the problem, pathophysiology, costs, clinical concerns, state-of-the-art therapeutic modes, clinical experiences to date with these methods, patient management requirements for the setting of care, and appropriate patient selection criteria which are required to provide for safe and effective therapy were provided in this forum. In addition, the future research agenda for the clinical management of these patients was highlighted, and the current regulatory, coverage and reimbursement policies governing these technologies were discussed. Other workshop topics included the classification and documentation of this disease condition and the clinical decision-making process and various provider responsibilities in the selection and monitoring of such care.

These concerns are all pertinent to managing the quality and cost-effectiveness of care of these patients. The day-to-day patient care expertise, academic and research experience, and knowledge of public policy processes of the invited speakers and panel members were of immense value towards forming a common basis for discussion and agreement, posing questions, advancing the dialogue, and setting the stage for possible resolution of perceived problems. The productive interaction, contributions and cooperation of public and private parties in this workshop were appreciated and of critical aid in determining issues of appropriate management. It is hoped that these formal presentations, roundtable discussions and panel consensus-type recommendations will be of significance and of practical use to decision makers who must decide issues of appropriate, reasonable and necessary treatment, as well as of interest to the practicing community of clinicians and caretakers who deliver care to these patients.

**PRESSURE ULCERS**

A pressure ulcer or pressure sore is defined as an area of localized tissue damage which is caused by ischemia due to forces of pressure. A pressure ulcer can be characterized by the depth of tissue loss, its location, its dimensions, and the degree of evidence of healing or necrosis. The term, decubitus ulcer, which has been used to describe this problem, is actually not an accurate description since such ulcers can develop when the patient is in a sitting position. It has been estimated that 3% to 5% of patients admitted to U.S. hospitals have or develop pressure ulcers. The incidence of pressure ulcers appears to be highest in the elderly population. The development of a pressure ulcer among elderly patients and the failure of such ulcers to heal have also been associated with a higher complication rate of infection and sepsis, and an increased risk of mortality.

The etiology of pressure ulcers is multifactorial. Four elements appear important in the development of a pressure ulcer: pressure, shearing forces, friction and moisture. When capillary blood circulation is reduced by an external force or pressure, then ischemia can develop and lead to tissue damage. This is more likely to occur where soft tissue overlies bony prominences. Patient-related characteristics which also are important factors in the development of pressure ulcers include level of activity, mobility, nutritional status, incontinence, circulation and oxygenation of tissues, and additional disease conditions or comorbidities.

The most basic element of management of these patients is the relief of pressure. If pressure is not relieved to a value below capillary closure, then it may be that other approaches will not result in effective healing of the pressure ulcer. Devices which are intended to consistently reduce interface pressure below capillary closing pressures are termed pressure relief devices. Air-floating bed technologies provide pressure relief. Devices which do not reduce pressure below capillary closing pressures are classified as pressure reduction devices, and include such items as alternating pressure pads, water mattresses, gel pads, and foam devices.
PART III. CLINICAL AND TECHNICAL ISSUES RELATED TO THE USE OF AIR-FLOTATION BED TREATMENT IN THE HOME SETTING

1. Overview and Clinical Definitions:
   Problem Definition of Pressure Sores

Glenda Motta, RN ET, MPH

Ms. Glenda Motta began the workshop presentations by describing the clinical problem of pressure ulcers. She emphasized that this was a significant national health problem, and stated that the best approach was prevention. For the preferred nomenclature in current practices, the International Association for Enterostomal Therapy (IAET) classifies those as "pressure ulcers" or "pressure sores" rather than "decubitus ulcers". This terminology evolved because the etiology of these ulcers, namely the critical factor of pressure, became known and accepted. The most significant contributing factors to the development of pressure ulcers were noted to be pressure and time. Ms. Motta also identified intrinsic factors which have been linked to a patient's vulnerability to developing pressure ulcers. This list included immobility, nutrition, hydration, circulation, oxygenation, moisture, sensory loss and psychological factors. The factor of age greater than 65 years was also identified, but this may be dependent upon its association with other chronic conditions. In terms of significance, causative factors may be ranked as follows: 1) Pressure; 2) Moisture; 3) General Health Status; and 4) Nutrition.

According to the IAET Standards of Care: Dermal Wounds: Pressure Sores, the staging of pressure ulcers is based on the depth of tissue destruction. Four distinct stages are identified. A Stage I ulcer is defined as erythema not resolving within 30 minutes of pressure relief. The epidermis remains intact. A Stage I ulcer is reversible with intervention. A Stage II ulcer is partial thickness loss of skin layers, involving the epidermis, and possibly penetrating into but not through the dermis. It may present as blistering with erythema and/or induration. The wound base is moist and free of necrotic tissue.

A Stage III ulcer involves full thickness tissue loss that extends through the dermis to involve subcutaneous tissue. This can present as a shallow crater unless covered with eschar. A Stage III ulcer may include necrotic tissue, undermining, sinus tract formation, exudate, and/or infection. A Stage IV ulcer is characterized by deep tissue destruction extending through the subcutaneous tissue to fascia, muscle layer, joint and/or bone. This is a deep crater, and may include necrotic tissue, undermining, sinus tract formation, exudate, and/or infection. If a wound involves necrotic tissue, staging cannot be confirmed until the wound base is visible.

The distribution of Stage III and Stage IV sores was estimated to range between 10 to 30 percent of all pressure ulcers, and Stage I and Stage II sores compose the remaining majority or 70 to 90 percent of all ulcers. The populations at risk for developing pressure ulcers are the young neurologically impaired, the elderly and the hospitalized patients. The overall incidence of pressure ulcers is difficult to pinpoint, but estimates of incidence for hospitalized patients range from 3 to 30 percent. The total prevalence of this condition is estimated at between 3.5 to 5 million individuals in the United States, and an estimated 60,000 deaths occur each year which are related to pressure ulcers.

Pressure ulcers affect the elderly in disproportionately high numbers. Seventy-two percent of pressure ulcers occur in patients aged 65 years or older, and an estimated 10 percent fraction of the elderly population will develop pressure ulcers in their lifetime. Nearly all or 95 percent of pressure ulcers develop over bony prominences found in the lower half of the body, with about 67 percent occurring around the hips and buttocks area, and 24 percent found on the lower limbs.

The costs associated with the management of pressure ulcers are significant.
A few years ago, it was estimated that the total cost of pressure ulcers, which included expenditures for nursing care and devices, was $6.5 billion. This figure represented a 1.5 percent fraction of the national health care expenditures. The literature which is currently available cites costs to treat and heal Stage I and II ulcers as high as $14,000 to $25,000, and costs to treat and heal Stage III and IV ulcers as much as $30,000 to $65,000 per case.

For purposes of this presentation, the term, air-flotation bed treatment, is used to refer to both the air-fluidized bed or bead bed, and the low air-loss bed. The rationale for categorizing these two types of beds together is their similarity in therapeutic intent, insofar as they both consistently reduce pressure below capillary closing pressure. Other devices which are used to manage pressure ulcers such as alternating pressure pads, water mattresses, gel pads, air-support mattresses and high density foam may not consistently reduce pressure below capillary closing pressure, and are termed pressure reducing devices. A consensus of opinion is needed on the common terminology for air-fluidized and low air-loss beds.

II. Physiology of Pressure Sores

G. Allen Holloway, Jr., M.D.

Dr. Allen Holloway discussed the physiology of pressure ulcers and the identification of risk factors for their development and progression. He defined a pressure ulcer as a skin ulceration that was associated with external pressure loading. Staging criteria have been used as clinical tools to grade sores according to their appearance and skin surface, but do not provide information about etiology or causative factors.

Implicated causative factors were identified as pressure, ischemia, anatomic configuration, tissue type such as skin or muscle, time/duration, scarring, metabolic state - local and general, position, shear forces, nutrition, infection, and moisture. There have also been questions raised about the contribution of factors such as blood viscosity and red blood cell conformability. Pressure is probably the single factor most often associated with the development of ulcers. And experimental studies have demonstrated that the application of pressure can lead to the formation of sores. However, pressure has really only been measured on the surface, and researchers have only minimally examined pressure factors and interactions beneath the level of the skin in deeper tissue layers.

Dr. Holloway pointed out that the cellular processes involved in the pathophysiology of pressure ulcers remain largely unknown, and what is observed, i.e., the pressure ulcer itself, is the endpoint of a complex physiological process which has resulted in tissue necrosis. The body of studies on pressure forces has been performed to answer the question of how much pressure the tissue type can tolerate without resultant tissue injury. However, in these studies, only surface pressure has been measured, and most of these studies have been performed on young and healthy subjects. Therefore, additional studies using different at-risk patient populations would be useful in further elucidating the pathophysiology of pressure ulcers. Also, although the obvious endpoint is the pressure ulcer, an endpoint which can be measured earlier in the development of the ulcer is needed for purposes of research.

A diversity of findings related to the relationship of pressure and time required to form an ulcer is found in the literature. This relationship is important because it indicates the "safe" or "unsafe" pressures which can lead to cessation of blood flow, ischemia and eventual tissue injury. The traditional measure utilized by clinicians has been the capillary closing pressure of 32 mmHg. One study has demonstrated that in normal subjects, skin surface pressures in the range of 100 to 150 mmHg were required to cause total cessation of blood flow. In a similar study conducted in elderly and more compromised patients, as little as 20 mmHg resulted in reducing capillary blood flow. This finding is in marked contrast to the normal subjects, and demonstrates the variation among individuals, and the increased vulnerability to pressure effects in the elderly.
more severely ill and malnourished patient population.

Dr. Holloway described some of his research activities to find markers which indicate when cellular death occurs. These activities have involved the measurement of capillary blood flow in skin by laser Doppler techniques. In one study, after 15 minutes of lying in a hospital bed, changes of reactive hyperemia were documented in normal subjects. These changes, which are indicative of ischemia, demonstrate the effects of pressure occurring in a very short time frame. Another study examined the blood flow in paraplegic patients placed on a variety of cushion devices. The results varied among individuals and among devices, and point out the pressure ulcers.

Dr. Holloway then outlined questions remaining about the etiology of pressure ulcers. Questions related to the topic of anatomy included: 1) Are all tissues affected equally? 2) If not, which tissue is affected first? 3) Are hard and soft sites affected similarly? 4) Does muscle breakdown occur with intact skin? and 5) Does scarring make the tissue more susceptible? He noted that there is evidence to suggest that fat, muscle and fascia layers are more susceptible to ischemia than skin, and may be affected prior to the changes observed on the skin surface. But measurements of changes in deeper tissue layers are needed to examine these processes.

He also listed questions related to factors other than pressure. These included: 1) Can other factors add to the pressure effect? 2) Do shearing forces interact with pressure effects? 3) Can cellular viability be determined at a point in time? 4) Are there one or more specific variables that can be used as a measure of tissue viability? 5) Why is there a discrepancy between viability time in pressure application studies and in reimplantation of amputated digits? 6) Are there differences between acute and chronic effects? and 7) Can animal studies or models be extrapolated to humans? Other factors such as shear force and nutritional status appear to contribute to the pressure phenomenon, but objective measurements of such effects are needed. There is evidence from animal studies which suggests that there are probably additive changes and decreased tissue tolerance with repeated pressure loading, but methods to monitor and distinguish such processes are presently lacking. Much of the previous research on this topic has been performed on animals, and the findings have been extrapolated to humans. However, these tissue types may not be strictly comparable, particularly in animal models other than the pig, and this disparity may alter the applicability or implications for humans.

Dr. Holloway concluded by stating that pressure ulcers are indeed caused by pressure effects. But the role of other causative factors, the local metabolic processes, and differential tissue responses are topics for future research. Poor nutritional status has been commonly identified as a risk factor, but this relationship requires additional documentation.

III. Macro Costs of the Management of Pressure Sores

Jane Kruger, RN

Ms. Jane Kruger presented a study that was performed at the Dallas Rehabilitation Institute on the resource needs required for pressure ulcer management. The principal investigator was Linda Dean, RN, of the Dallas Rehabilitation Institute. In this study, a medical chart review was performed for a group of 50 consecutive patients admitted to the spinal cord injury unit. The age of the patients ranged from 20 to 45 years. The mean length of time post-injury was 6 years, and ranged from 30 days to 25 years. The average hospital stay was 66.5 days and varied between a minimum of 11 days to a maximum of 191 days.

This study was undertaken for the purpose of examining the resource requirements for the treatment of pressure ulcers in the spinal cord injury patient population. A review of the literature revealed that no such studies in the past seven years had been reported. The resource consumption profile for hospitalization included the hospital bill, the attending physician’s charges, the plastic surgeon’s fee, and related equipment and
surgical fees. This profile did not include charges for radiology, pathology and laboratory, consultations, or previous hospital bills.

The characterization of the study population was as follows. Pressure ulcers were generally located in the ischial tuberosity, sacrum and trochanter areas, and their etiology was believed to be a result of inadequate skin care in 35% of cases. Other less common causes of ulcer formation were as follows: falls, unstable old scars, abrasion/scrapes, W/C cushion probes, tight clothing, orthotic devices and spasticity. The size of the ulcers ranged from 1 x 1 cm to 15 x 15 cm, and averaged 5.3 cm x 4.74 cm.

Medical modalities which were used in these patients included wet-to-dry dressings, whirlpool, local creams, ointments and vitamins, oral vitamins and aggressive nutritional programs. The list of medical complications included anemia, wound infection, malnutrition, spasticity, and scoliosis. The different bed treatments included air-flotation beds, egg crate mattresses, kinetic beds, regular hospital beds, air-flotation mattress, and alternating air mattresses. Thirty-five of the fifty patients were treated with a bed technology. Patients who were selected for the air-flotation bed remained on the bed for an average of 34.5 days, and total days of bed treatment ranged from 2 to 156 days.

Methods of surgical intervention included flap surgery, graft procedures, tendon releases, or debridement. Nine patients received no surgical intervention.

According to the previous resource profile, the average cost per patient with a Stage III or IV ulcer and a cervical cord injury was $91,271. The average cost per patient with a Stage III or IV ulcer and a thoracic cord injury was $56,181. The average cost per patient with a Stage II or IV ulcer and a lumbar level injury was $42,984. For the study population, the costs for treatment ranged from $10,500 to a high of $195,480, and averaged to $69,587 per case. In conclusion, Ms. Kruger noted that the study findings demonstrated that costs are enormous for the treatment of pressure ulcers in this population, and recommended that investment should be directed towards prevention of the problem, and that future research is needed for more rapid treatment modalities.

IV. Financial Impact on Medicare Program

Flora Chu, M.D.

Dr. Flora Chu presented the findings of an analysis of the national expenditures for the treatment of pressure ulcers in the elderly and total patient population. The Medical Technology and Practice Patterns Institute performed an analysis of the volume of services and type of resource utilization required by patients with the diagnosis of decubitus ulcer (DU), based on two major data bases: the Medicare hospital billing claims file and the National Hospital Discharge Survey. The term, decubitus ulcer, is not an accurate description, but because these ulcers are classified as decubitus ulcers in these data bases, this term will be used for the remainder of the discussion. The figures refer to incidence rather than prevalence, because the data are reported as hospital discharges. In summary, the overall findings corroborated the general clinical observations which have held that the patient population hospitalized with a diagnosis of decubitus ulcers has a greater-than-average severity of illness and appears to be at a higher risk of morbidity and mortality, that this patient population is sizeable in terms of volume, and that the resource intensity and length of hospitalization required for the care of these patients is significant.

The number of Medicare cases that were admitted with a primary diagnosis of decubitus ulcers was about 26,000 in the year 1987, and the number of cases with decubitus ulcers listed as a secondary diagnosis was about 96,000. The total was about 122,000 cases. For every one case with the primary diagnosis of an ulcer, there were nearly 4 cases with the secondary diagnosis. Cases presenting with decubitus ulcers as the reason for their hospitalization composed about one quarter of a percentage point of all cases under PPS, and all cases with the diagnosis of an ulcer totalled about a 1% fraction of all Medicare discharges.
The results of the mortality case experience were striking. The in-hospital mortality rate for patients with the primary diagnosis of DU was about 11%, and the rate for patients with the secondary diagnosis of DU was about 17.5%. For all cases with a diagnosis of ulcer, the mortality rate was 16%, which was over twice as high as the average of about 7% for all hospitalized Medicare patients. The mortality rate for the general category of chronic ulcers of the skin was much smaller or 4%. These patients appear to be among the more critically ill patients in the Medicare population.

The average hospitalization for patients with a primary diagnosis was about 20 days, and the average length of stay (LOS) for patients with a secondary diagnosis was 18 days. These are significant lengths of hospitalization, since the average Medicare stay under PPS was only 8.5 days in 1986, or less than half as long. The total days of care summed to about one half million for patients with the primary diagnosis, and about one and three quarters million for patients with the secondary diagnosis. These findings appear to support the resource intensity and lengthy inpatient management required for these cases, or about twice as great as the average case.

The average hospital charge for patients with the primary diagnosis was about $13,000, and the average charge for patients with the secondary diagnosis was $12,000. In comparison, the average hospital charge for a Medicare patient was $6,600, or about half as much. The total hospital charges for the care of all patients with a primary diagnosis were about $340 million, and the charges for all patients with a secondary diagnosis were a little over $1 billion, and, in total, was one and a half billion. Cases with the primary diagnosis of decubitus ulcers accounted for about a half of one percentage share of all Medicare hospital charges, and the share for all cases with a diagnosis of decubitus ulcers was about 2%.

The average Medicare payment for patients with a primary diagnosis was about $6,700, and the average payment for patients with a secondary diagnosis of DU was $5,500. Total Medicare reimbursements were nearly $180 million for cases with a primary diagnosis, and amounted to about $500 million for cases with a secondary diagnosis. The payment rate covered a little less than half of the charges for patients with a primary DU diagnosis, and covered a higher portion or about a 60% share of charges for patients with a secondary diagnosis.

Based on the 1986 National Hospital Discharge Survey, the following results were found for the national experience. For the category of cases with the first-listed diagnosis of decubitus ulcer, there were about 32,000 discharges, and the percentage of female patients was about 55%. Cases with a first-listed diagnosis of ulcers represented almost a tenth of a percentage share of all discharges nationally, and represented a larger share of the population most-at-risk, or about two tenths of a percentage share of the elderly population. The age breakdown of these patients was as follows: about 20% were found between 15 and 44 years of age, about 10% were found between 45 and 64 years of age; and a majority, or about two thirds of the total, were 65 years of age or older.

The regional breakdown of cases with a diagnosis of decubitus ulcer showed the following distribution: about a fifth share in the Northeast, another fifth in the Midwest, two-fifths in the South and close to another one fifth found in the West. Fewer patients were found in the Midwest than could have been expected, and more patients in the Northeast and in the South were identified than could be anticipated on the basis of total population figures alone. When comparing regions along measures such as total elderly population size, number of physicians and number of hospital beds, these relationships also appeared to hold.

In terms of all-listed diagnoses, there were 157,000 cases nationally. Patients with a primary or secondary diagnosis composed a 0.15% share of the total of all-listed diagnoses, and a 0.27% corresponding share of the elderly population. The total days of care for patients with the first-listed diagnosis of decubitus ulcer was 620,000. This was approximately a 0.3% proportion of all days of care, more than three
times greater than the corresponding share of the total volume of discharges. The average length of stay for a patient with a first-listed diagnosis of DU was 10 days. In contrast, the national average length of stay was about 6 days, and for elderly patients, the average LOS was about 8.5 days.

For patients with the first-listed diagnosis, longer hospitalization stays were found in the South, and proportionally shorter hospitalization stays were found in the West. The average length of hospitalization ranged from a low of 15 days in the West to a high of 22.5 days in the South. The Northeast and the Midwest regions had comparable lengths of stay of about 18 days. These regional differences might be attributable to overall variations in the hospitalization practices or patient mix, or might pertain, more specifically, to different practice patterns and different uses of outpatient services in the management of DU patients.

The rate of hospitalization for patients with a first-listed diagnosis of decubitus ulcer was about 140 per million population for the nation as a whole. For the total elderly population in the U.S., the hospitalization rate for the primary diagnosis of DU was about 770 per million elderly. For every 10,000 physicians, there was an average of 725 patients hospitalized, and for every 10,000 hospital beds, there was an average of 244 inpatients. Again, the greatest rates of hospitalization for the care of primary decubitus ulcer cases on a population basis were found in the South.

Dr. Chu summarized by stating that decubitus ulcers, or pressure ulcers, are an important clinical problem for the hospitalized population, especially the Medicare population. This problem is extended to outpatient settings of care and in the home, but reliable and complete information is more difficult to gather in these settings. The management of these patients can be relatively costly in terms of lengthy hospitalizations and resource use. Moreover, these patients are at a higher risk of mortality than the average Medicare inpatient. Medicare payment levels also are likely to fall significantly short of provider charges, and cover, on average, a little less than half of the hospital charges for patients presenting with the primary diagnosis of decubitus ulcers. Different geographic regions varied in their rates of hospitalization for cases with decubitus ulcers, and in their patterns of length of hospitalizations.

V. Clinical Experience with Air-Flotation Bed Technology - Part 1

Richard M. Allman, M.D.

Dr. Richard Allman gave a presentation on the clinical experience with air-flotation bed technology in the hospitalized population. He began by describing his research activities on the prevalence of pressure ulcers in an adult hospitalized population. He performed a cross-sectional survey of the adult inpatient units in the Johns Hopkins University Hospital in March, 1984. The objectives of this study were to determine the prevalence of pressure ulcers, to identify patient risk factors, to determine the different preventive and treatment interventions used, and to quantify hospital charges, length of stay and hospital mortality. He subsequently carried out a randomized, controlled trial of air-fluidized beds and conventional therapy for patients with pressure ulcers. The purpose of this trial was to determine the effectiveness, costs and complications of treatment with the air-fluidized bed.

Dr. Allman defined the condition of a pressure ulcer as the loss of epithelium, skin breakdown, the presence of a blister, or skin necrosis manifested as an eschar formation over a bony prominence. He pointed out that erythema over a bony prominence may not be reliably enough assessed for the purposes of research studies. The prevalence of pressure ulcers reported in the literature ranges between 3 to 11 percent in a population found in an acute hospital setting, and the rate of incidence ranges between 1 to 3 percent. He stated that his studies suggest that between 18 and 28% of bedridden hospitalized patients have pressure ulcers, with an incidence rate of 7.7% over a three week follow-up among such high-risk patients. About sixty percent of patients having pressure ulcers developed them while they were
hospitalized, according to a number of sources in the literature.

In the cross-sectional survey at Johns Hopkins Hospital, Dr. Allman identified 30 patients with pressure ulcers and also identified a group of 78 hospitalized patients who were at risk for the development of pressure ulcers because they were expected to be confined to bed or chair for at least one week. The thirty patients with pressure ulcers had a mean hospital stay of 49.6 days compared with a mean length of stay of 39.4 days for the 78 patients who were at risk. The median length of stay was 46 days for those patients with ulcers, and was 26 days for those patients who were at risk.

The mortality rate was 4.5 times greater for at-risk patients developing pressure ulcers during the study period compared with those who did not develop ulcers (67% vs. 15%, respectively). This observation was consistent with previous studies which have shown an increased mortality rate for patients who developed pressure ulcers. For patients who demonstrated improvement in their pressure ulcers during the randomized trial, the associated mortality rate was 10.5%, but for patients who did not demonstrate improvement in their ulcers, the corresponding mortality rate was 41%. However, this increase in mortality rates may not be totally attributable to the condition of pressure ulcers, since these patients also have comorbidities and serious underlying disease conditions.

The patients at risk for sores were assessed weekly for up to three weeks or at discharge from the hospital to reassess pressure ulcer status. The patients who were identified as at risk and developed pressure ulcers tended to have lower serum albumin levels, were more likely to be incontinent of stool, and had the diagnosis of fracture more often than the group of patients who did not develop ulcers. These three factors were significantly associated with having pressure ulcers but the difference in serum albumin level between at-risk patients who developed sores and those who did not was not statistically significant. Dr. Allman reported that he is expanding this type of study in order to examine prospectively a much larger group of elderly, hospitalized patients of approximately 900 in number at the University of Alabama Hospital. This larger study will permit identification of risk factors that contribute to the development of pressure ulcers among hospitalized patients with limited mobility.

Dr. Allman noted that the best study available in literature which demonstrated the effectiveness of preventive measures was conducted by Anderson et al in Sweden in the early 1980s. This study examined the use of water mattresses and alternating air mattresses in hospitalized patients. The study revealed that the incidence of pressure ulcers decreased by more than 50% in patients receiving such treatment and provided evidence that pressure reducing devices decrease the risk of ulcers in hospitalized patients.

Dr. Allman also described a recent review that he had performed at the University of Alabama on the institutional use of specialized beds and mattresses for the prevention and treatment of pressure ulcers. The most commonly used device for the prevention of pressure ulcers was a convoluted foam mattress. The annual institutional expenses for convoluted foam mattresses was $80,394 while the corresponding expenses for Solf-Care mattresses were about $17,027. The use of air-flotation beds, which included both air-fluidized beds and low air-loss beds, totalled an estimated $226,000 in 1985, and was projected to increase to about $711,000 for 1987, based on the fourth quarter expenditures. The concern over the rising expenditures for the use of air-flotation beds led to the establishment of an educational program for physicians to learn more about the appropriate use of these beds.

Dr. Allman also described the findings of the prospective, randomized, controlled clinical trial in more detail. His research protocol at Johns Hopkins University Hospital examined the application of air-fluidized beds versus "conventional therapy." Conventional therapy included repositioning every two hours and the use of an alternating air-mattress covered by a foam pad on a regular hospital bed for patients with pressure ulcers. The selection criteria
included patients who were confined to bed or chair, who had an expected life expectancy of at least one week, and who had a pressure ulcer located on the sacrum, buttocks, back or trochanter. A total of 65 patients were randomized and completed the trial, with 31 receiving air-fluidized bed therapy and 34 receiving conventional therapy. The two patient groups were similar in terms of health status and pressure ulcer characteristics but the patients assigned to air-fluidized beds had greater limitations in activity level.

The findings of this controlled trial showed that 71% of patients improved on the air-fluidized beds, compared to 47% of patients on conventional beds. The patients receiving an air-fluidized bed were found to have an improvement rate which was one and one half times that for patients receiving conventional therapy. The differences between the two patient groups were significant for the larger sores, but the outcomes were not significantly different for smaller sores, or sores less than 7.8 cm² in size. No significant differences in response rate were found between patients with superficial ulcers and patients with deep lesions. Factors which were associated with the failure to show improvement included a lower protein and calorie intake, a higher white cell count, a higher serum creatinine level, larger size ulcers, deep ulcers, a history of a skin graft or flap for a sore, and a reduced urine output. After adjusting for the type of therapy, protein intake and white cell count, no other factors, including size and depth of sore, remained significantly associated with sore outcome. Twenty percent of the study patients were discharged to nursing homes although only one patient was admitted from a nursing home.

In this trial, nurses were also surveyed regarding the effectiveness and ease of applying the two therapeutic modes. The findings indicated that nurses generally thought that the patients receiving air-fluidized bed therapy healed faster, and had fewer new skin breakdowns. However, nurses indicated that it was more difficult to transfer patients and to position patients in the air-fluidized bed than with the conventional bed. Patients reported decreased levels of pain and improved comfort with the air-fluidized bed. The trial results suggested no significant increase in adverse effects with the use of the air-fluidized beds. The occurrence of problems such as pneumonia, urinary tract infection, sepsis, low urine output, heart failure, and electrolyte imbalances were not statistically different for the two groups of patients.

Dr. Allman concluded by discussing the reporting of pressure ulcers in the hospitalized population. In a re-examination of the data collected during the randomized, controlled trial of air-fluidized beds at Johns Hopkins University Hospital, out of 140 patients identified on the wards by the nursing staff as having pressure ulcers and who met eligibility criteria for the trial over an 18 month period, only 31% of this group had the ICD-9-CM diagnostic code of 707 at discharge among all five top-listed diagnoses. This finding indicates that the prevalence of pressure ulcers in the hospitalized population is underreported to a very significant degree. This may be because most patients have multiple comorbidities, which are regarded by physicians as more important or of higher priority. Thus, pressure ulcers are not included in the limited list of diagnoses which are coded on the claims form. Therefore, it is difficult to describe or to estimate the true dimensions of this health problem, based upon discharge records or billing information alone.

VI. Clinical Experience with the Air-Fluidization Bed Technology - Part II

Roseann B. Myers, RN, CETN

Ms. Roseann Myers began her presentation by stating that there was a need to change officially from the outdated nomenclature of "decubitus ulcer" to the current term, "pressure ulcer." This change would facilitate the education of patients and caregivers with regard to the etiology of the ulcers and also, with regard to the therapeutic intent of medical devices and the need to reposition patients. She also stressed the critical element of nursing care in the management of pressure ulcers. The current nursing shortage may be a factor in contributing to an increased incidence of pressure ulcers, because of the lack of staffing
and deficiencies in nursing resources for the appropriate care of patients. Nurses are also under the scrutiny of review in these situations, because the development of pressure ulcers has been linked to monitors of quality of care in institutions. However, she pointed out that pressure ulcers can develop within a time frame as short as twenty minutes to two hours, and that even the frequent positioning of a patient cannot prevent some types of skin breakdown from occurring. She related an incident in which a 93-year-old developed an ischemic area only fifteen minutes after having been repositioned, and subsequently developed a full thickness wound.

Ms. Myers also explained that the staging of the pressure ulcer did not, in itself, constitute a wound assessment. More information is needed about severity of the wound, its location and the ability to heal in order to assess thoroughly the patient’s condition and treatment needs. Additional factors which need to be described in such an assessment include the wound margins, wound base, condition of the tissue, presence of necrotic versus granulated tissue, and physical status of the patient, as well as information about the depth of the wound.

Ms. Myers pointed out some of the benefits and costs associated with air-flotation bed treatment in the home setting, based on her own clinical experience. Air-flotation bed technology is an effective therapy for pressure ulcers in select patients, when appropriately used in the home setting. Air-flotation beds at home also facilitate caregiving for pressure ulcer management in the home. Many of these caregivers for patients are themselves elderly or even frail, and it would be difficult for them to position the patient frequently and at regular intervals throughout the day. Education and training of the patient and caregiver is very important to ensure and maintain appropriate care, and should be reinforced. However, the preparation and requirements for placing and operating the technology in the home setting are considerable. She reported one case in which the use of an air-fluidized bed therapy in the home setting increased the patient’s monthly electricity bill by $80. This posed a significant financial burden for the patient, which was not reimbursable by his insurance plan.

With the introduction of air-flotation bed technology, a new clinical situation arises concerning the appropriate management of these patients. When should one "step up" to these specialized beds from other therapies, and when should one "step down" from these beds to other therapies? She described the problem of a new skin breakdown occurring after a wound had been healed, which can result once a patient is taken off an air-fluidized bed to other types of therapy which provide less pressure reduction or can result if a patient is not provided with any type of pressure reducing device. This outcome occurs because of the altered skin integrity and vulnerability to injury. Even once the skin is apparently healed, its integrity is only 80% of normal. It was noted that the healing process of the underlying supportive structures require on the order of at least 21 days. Although epithelialization may be complete, there may still be ongoing healing of the deeper layers and full strength is not yet recovered.

Instead of an abrupt switch to devices which provide less pressure reduction or none at all, Ms. Myers proposed that there may need to be a "weaning" process. This treatment plan would be devised to decrease more gradually the dependence on an air-fluidized bed and to allow time for increased tissue tolerance. Others in the audience concurred that this was an important component of management, i.e., when to "step-up" to air-flotation bed treatment, when to "step-down" and how best to "step-down" to other modalities of treatment in order to maintain the benefits and outcome achieved by use of the air-flotation bed technology.
PART IV.  POLICY ISSUES IN THE INTRODUCTION OF AIR-FLOTATION BED TREATMENT IN THE HOME SETTING

VII. Panel Discussion on Patient Management
Concerns for the Home Use of Beds

Marie Brown-Etris RN, ET
Janet La Mantia, MA, RN, CRRN
Ruby VanCroft, RN

The panel discussed the management of a patient on air-floatation bed treatment in the home setting. These concerns are relevant to the delivery of care in the noninstitutional setting. Ms. Brown-Etris stated that the major objectives of providing this care are to maintain the health status and comfort of the patient in his/her own home, and to avoid the need for costly and resource-intensive hospitalizations or institutionalized care. The lack or inadequacy of reimbursement by third-party payers can be a significant obstacle to providing care in this setting. This poses a problem because at the current time, Medicare reimbursement to the home health agency is only made for the purposes of post-debridement care for an unspecified length of time. If a specialized bed is placed into the home, the denial for reimbursement of the equipment expenditures could come much later, and the home health agency must then absorb this expense. In addition to denials of reimbursement for the bed treatment, which places financial burdens on the provider and/or the patient, the patient could also face increased and significant out-of-pocket expenses for the placement and operation of the bed in the home.

Requirements of documentation for payment purposes were emphasized, including accurate and precise characterization of the wound, description of the progression of wound healing and the outcome which was achieved with the treatment. This documentation is important for third-party payers to assess and validate the reasonableness and necessity of care using this specialized bed therapy, and its contributions to improved patient outcome. Some participants also observed that the case of air-floatation bed technology could be likened to other specialized technologies in the home, i.e., home dialysis, ventilators, and total parenteral nutrition. Perhaps the placement and payment policies for air-floatation bed treatment could follow precedents and benefit from lessons in earlier cases of specialized technologies, which were introduced into the home setting.

Ms. LaMantia noted that in the clinical literature, there are no known published studies of the application of air-floatation beds in the home setting. Instead, it appears that the main body of evidence on their use consists of clinical experiences and reports in the home setting, and extrapolation of study findings from their extensive use in the institutional setting. These beds have been used in the home for patients with pressure ulcers and who continue to be at high risk for developing additional or recurrent sores, and thus, at risk for repeated admissions for pressure ulcer management. In the West, the use of air-floatation beds in the home setting has been more common than in other parts of the country. The Chairman of the Rehabilitation Nursing Foundation, Cynthia Bachman, RN, MSN, reported that there were several medical centers, mostly located in the Western United States and in Texas, which have discharged select patients from the hospital to the home setting with the air-floatation beds. She also noted that in these areas, Health Maintenance Organizations considered it to be a more cost-effective practice to reimburse for the use of these beds in the home setting than to pay for the bills of repeated hospitalizations.

Based on her clinical experience and interviews with clinicians, Ms. LaMantia presented the following reasons which support the usefulness of air-floatation beds in the home setting. Air-floatation beds have been useful in maintaining patients with recurrent sores and spinal cord injuries out of the hospital, and as a result, total health care expenditures are reduced. A patient could be discharged earlier from the hospital if these beds were used in the home setting. Also, a patient could be discharged from the hospital earlier and then continue the healing process at home and
become fully healed, which is a requisite before being admitted to an active rehabilitation program. As previously mentioned, it would be easier for elderly caregivers to manage a patient at home with the use of an air-flotation bed treatment rather than meeting the demands of frequent positioning. For example, demands upon the home caregiver would be less burdensome for managing a highly spastic patient on an air-flotation bed than on a conventional treatment regimen.

Ms. VanCroft emphasized that another critical element in the delivery of air-flotation bed treatment in the home setting is the responsibility for clinical supervision and monitoring of care. Nurses in the community are responsible for visiting patients on a regular basis and are essential to the assessment and care of patients with pressure ulcers. The placement of these beds in the home is intended for the management of an acute condition and would be reimbursed for this purpose. The bed treatment is not intended to be a permanent strategy for case management. Therefore, the assessment of the wound and the patient’s needs for the bed treatment and ability to respond satisfactorily to other available treatments are evaluated and re-evaluated on a continuing basis. This is necessary in order to validate the continuing use of the specialized bed treatment.

The home health staff needs to be properly trained and educated about the appropriate use of this bed treatment. It was also noted that formalized protocols may need to be established for the use of these beds. Instruction about the use of technology in alternative settings of care may be an appropriate addition to professional educational programs for physicians, nurses and other providers. It is expected that shorter hospital stays, which are now encouraged in this climate of cost-containment and DRGs, would result in placing patients with pressure ulcers in the home at varying levels of care requirements, severity-of-illness and resource needs. This practice also suggests the need for planning and coordinating community health resources prior to the patient’s being discharged home. The objective of this planning activity is to maintain the medical benefits and results which have been achieved in the hospital setting.

A key element of the treatment strategy is the education and training of the patient and the family or primary caregiver in the home. The home health team is responsible for this education and training. Components of this training include teaching about proper wound care, infection control, turning and positioning the patient, as well as about the simple operation of the bed. An important member of the home health team would be a dietitian, who would work with the family in order to incorporate good nutritional value into their daily diet, and to accommodate their usual food likes and habits. The home health aide must also be able to reinforce this knowledge and training on a regular basis. Case management resources must be effective and be used efficiently in order to supply the best services to clients who are in need. Patient and caregiver education and training is important to achieve desired outcomes, although payers may question the medical necessity for such teaching and deny payment.

Technical and support requirements for the installation and operation of the specialized beds are also important in the home setting. These requirements include an accommodative entryway into the house, an adequate electrical and power supply, floor support, and reinforcement for the weight of the bed. Bed installation may even entail the involvement of town engineers for safety code approval. It was noted that the significant weight of the beds, i.e., the air-fluidized beds which weigh about 2,000 pounds, and the low air loss beds which weigh about 500 pounds, could pose a problem for the structural tolerance of ordinary houses. The family would need to be a willing and informed part of this decisionmaking process and be amenable to the disruption of their home and activities in order to accommodate the bed. Another requirement is for on-call technical services and back-up availability when the equipment fails to operate properly. These services are necessary in order to maintain the therapeutic value of bed treatment. However, there does not appear to be a safety risk to the
patient or family in case of equipment malfunction in these circumstances.

One ethical issue raised for discussion was the dilemma of resource allocation, i.e., which patients ultimately receive this treatment and which patients do not, and who should decide? Although this bed could be appropriate for treating specific patient categories, the limited payment rate or denial of third-party reimbursement, which is a problem particularly relevant for Medicare program beneficiaries, the budgetary constraints faced by providers of care in trying to absorb these expenses, and often, the limited ability of elderly patients to pay these bills from their own income, create a potential for bias in the access to these beds. Given the current reimbursement situation, it is more difficult and burdensome for patients with limited financial resources or for providers with restricted funds to afford this care.

Another ethical concern of the participants was the determination of appropriate treatment objectives for patients with a short life expectancy. It may be that the course dictated for healing of the ulcer conflicts with the course indicated for maintaining the terminally ill patient’s comfort and for reducing the patient’s pain. Dr. Allman noted that the expected mortality rate for patients with a pressure ulcer in the hospitalized population is high or about 35%. These questions will ultimately be faced in the treatment of the older, severely debilitated patient population.

Participants around the table also stressed the importance of preventive care. They reiterated that although reimbursement is not made in the home setting for preventive care, studies demonstrating its cost-effectiveness in comparison to the treatment of an existing condition are necessary. Also, for some patients, recurrence of their pressure ulcers is a common clinical problem and necessitates repeated hospitalizations and procedures for treatment. In these cases, an early intervention strategy would consist of maintaining skin integrity and healing after hospitalization. Gaining equitable reimbursement for the prevention of pressure ulcer development and reducing the recurrence of pressure ulcers is an worthwhile objective.

VIII. Panel Discussion on Proposed Patient Selection Criteria

Richard M. Allman, M.D.
Sr. Josephine Bryan, RN, MSN
Glenda Motta, RN ET, MPH
Roseann B. Myers, RN, CETN
Judy A. Wells, RN, BSN, CETN

The panel discussed establishing criteria for selecting appropriate patients for receiving the specialized air-flotation bed treatment in the home setting, as well as the practical and public policy considerations of applying such criteria. Participants acknowledged the significant expenses associated with this therapy, and the need to allocate resources to patients who would benefit from such care among those who do not demonstrate a satisfactory response when placed on less costly and less intensive treatments. This therapy should be used selectively, and its cost-effectiveness and cost-benefit ratio could become considerations in determining suitability for the home setting. It was reiterated that the air-flotation bed therapy generally is not intended for prevention of pressure ulcers, but is intended for the treatment of a defined disease condition.

Therefore, one of the objectives for the establishment of patient selection criteria is to distinguish a group of patients for whom this would be appropriate therapy, based on medical need. These criteria would specify both characteristics of the pressure ulcer, and of the patient and his/her underlying disease condition or health status. However, these criteria must also be responsive to the individual patient. The panel members and participants agreed that the criteria could not be set too rigidly, otherwise some patients who would truly benefit from this therapy would be excluded. Instead, there must also be room for flexibility and for providing care which is warranted by the individual clinical circumstances. The patient selection criteria should also take into account the appropriate goals of therapy and anticipated health outcome, which may vary from patient
to patient. The goals of care for such patients may include healing of a pressure ulcer, retarding progression of the ulcer to a deeper depth, inhibiting formation of new ulcers, pain management, and maintenance of comfort and integrity in the terminally ill patient, etc.

Third-party payers need to employ criteria which delineate reasonable and necessary indications for treatment. These will be applied in the determination of whether to pay for a service, under existing policy guidelines. Since the review of claims must be performed in an efficient and expeditious manner, criteria also need to be fairly simple and precise. Speakers also noted that third-party payers desire an accurate and complete description of the wound, of its progression in healing and of the measures of outcome and successful resolution. In a survey of ET Nurses, Ms. Motta reported that the following measures were found to be indicative of a satisfactory outcome: decreased ulcer size, decrease in staging classification number, e.g., from a Stage IV to a Stage III or Stage II ulcer, presence of granulation, absence of new ulcer formation, healing of the ulcer without need for operative intervention, no further deterioration of the existing ulcer(s), or improvement in the drainage/odor of the wound.

The panel and audience discussed several general patient characteristics which were believed to be appropriate for considering the option of air-flotation bed treatment in the home. These characteristics were selected on the basis of the providers' prior clinical experiences, expert opinion and findings from the literature. Dr. Allman suggested the following three patient categories, which were partially based on findings from his clinical trial of air-fluidized bed therapy: 1) patients with a larger ulcer, (a surface area greater than 7.8 cm²); 2) patients recovering from flap, graft or other reconstructive surgery for pressure ulcer resolution; and 3) patients suffering from recurrent ulcerations and an inability to heal on conventional therapy once discharged from the hospital. Also, based on findings from a survey of ET Nurses, Ms. Motta reported that the utilization of air-flotation bed treatment was believed to be helpful in patients with the following conditions: 1) multiple pressure ulcers; 2) a Stage II, III or IV pressure ulcer (using IAET staging classification criteria); 3) significant healing difficulties such as nutritional deficiencies or circulatory/oxygenation problems; 4) a Stage IV ulcer which requires operative intervention; 5) immobility with multiple organ system problems; 6) extensive burns; and 7) cancer with intractable pain.

Ms. Wells described the patient risk assessment program developed in her rehabilitation hospital setting, which had been employed in order to identify patients who would benefit from the use of air-flotation beds. The common factor among patients who are in need of such treatment is immobility. Increased length of immobility may contribute to the patient's risk of forming new pressure ulcers and to the patient's inability to heal existing ulcers. And the key to effective treatment is the relief of pressure. This risk assessment tool utilizes a simpler and more direct determination of the patient's needs in terms of pressure relief than the need for more complex assessment instruments which are already in use. The three important factors considered in the assessment are the following: the number of intact turning surfaces of the patient, the patient's ability to turn independently, and the availability of reliable caregiving in the setting of care, such as in the home. For example, a simpler bed overlay would be indicated for use if the patient had two or three turning surfaces free of pressure ulcers, and could reposition independently or had a reliable caregiver to provide assistance. If a patient had only one turning surface without a pressure ulcer or no turning surface at all, then an air-flotation bed treatment would be an appropriate choice, using these criteria.

Differences found among the available air-flotation bed technologies were important factors in treatment selection. For example, positioning the patient with the head of the bed greater than thirty degrees (high-Fowler's position) can be performed with the low air-loss bed, but not with the air-fluidized bed. It is also easier to transfer a patient in and out of the low air-loss bed than to transfer a patient in and out of the air-fluidized bed, particularly a larger patient. But Ms. Wells cautioned, too,
that there may be a possibility of a patient falling out through the side rails of an low air-loss bed. It was also mentioned that from studies found in the medical literature, insensible fluid losses have been documented with the use of the air-fluidized beds. Therefore, in patients who are vulnerable to fluid imbalances and dehydration, this feature would be a factor in selecting the low air-loss bed over the air-fluidized bed. Also, some participants noted that patients lying in the air-fluidized bed sometimes become disoriented and confused.

Members of the panel and audience discussed which bed technology would be best for burn patients. However, there were no burn care experts at the meeting to provide the specialists' consensus on this matter. Dr. Allman noted that the air-fluidized bed therapy had been used for the management of burn patients, perhaps because of the beneficial "drying" effect for patients with draining wounds, and that both types of beds were being used now in the burn care unit at his institution. Dr. Holloway reported that at his institution, burn patients were managed exclusively on the low air-loss beds. This strategy was devised because of the need for frequent transfer and mobility of patients in and out of bed, and in order to avoid the fluid losses associated with the air-fluidized beds. Additional data and outcomes from other medical centers will be needed to clarify this issue.

Ms. Wells outlined the following indications for selecting a type of air-flotation bed technology, given that the patient medically warrants such treatment. These indications were based upon her institution's experience.

I. Clinical indications for the selection of a low air-loss bed were: a) a patient has three intact turning surfaces and but repositioning is limited due to a medical condition requiring a high-Fowlers position, e.g., cardiopulmonary compromise; b) a patient has only one intact turning surface regardless of his/her ability to turn independently or the availability of help in the home setting to assist in turning; c) a patient requires frequent transfer in and out of bed; d) a patient is vulnerable to fluid losses and dehydration; and e) a burn patient.

II. Patients for whom an air-fluidized bed is clinically indicated include: a) the severely debilitated patient who has no turning surface, regardless of mobility or available assistance; and b) a patient who has undergone reconstructive surgery for a pressure ulcer.

IX. Panel Discussion on Future Research Issues

Katherine Jeter, Ed.D., ET
G. Allen Holloway, Jr., M.D.

The panel discussed unresolved issues concerning the etiology and pathophysiology of pressure ulcers, and the prevention and treatment of sores, and developed suggestions for establishing a research agenda. The consensus in the community has been that pressure is the most important and basic factor in the etiology of pressure ulcers. But this acceptance does not mean that knowledge about the development of pressure ulcers is complete, or that we can afford to be complacent about striving to learn more about the underlying pathophysiological processes. Few research activities have been directed at examining the cellular processes involved in pressure ulcer formation. It was pointed out that additional research studies are needed to describe the effects of pressure forces at the cellular level. The pressure ulcer and the necrotic tissue are the observed endpoints and results of an intricate process, but the pathophysiology of ulcer formation needs to be better characterized. Another issue to be explored is the role of tissue tolerance, and the differences which are found among patients in their vulnerability to ischemia and tissue necrosis.

Dr. Holloway emphasized that more objective endpoints are needed in order to view pressure ulcer development at earlier stages and to identify when changes are occurring within cells. For example, these endpoints could incorporate measures of biochemical processes such as protein synthesis. Mechanisms of tissue injury include reduced blood flow and tissue oxygenation, and these topics could be examined in greater detail, using measures of flow and transcutaneous oxygen. The effects of shear
forces on tissues could be examined objectively with these endpoints. Also, the differential responses of tissue types in the development of pressure ulcers and in the healing processes need to be characterized more thoroughly.

Dr. Holloway also described some newer, more sophisticated techniques which are being used to study early cellular changes. One method was the photographic mapping of skin surfaces and the identification of NADH fluorescence. The reduction in NADH fluorescence would suggest ischemic changes. Presently, researchers are examining the use of nuclear magnetic resonance spectroscopy to identify changes in phosphorus metabolism and protein synthesis.

Some participants emphasized that preventive modes require additional investigation and study. For instance, much attention has been focused on the relationship between nutritional status and the development of sores and the ability to heal, but more objective evidence should be gathered. This effort may need to include establishing baseline nutritional assessments, measuring nutritional status, and determining adequate nutritional intake.

Dr. Jeter described concern over the contribution of the condition of pressure ulcers to mortality. Previous studies have found an association between having pressure ulcers and a higher mortality rate. However, these patients are also likely to have comorbidities, and this relationship complicates the attribution of causality. Instead, it was suggested that, in conjunction with studies that adjust for severity-of-illness measures, such as the application of the APACHE system and other case-mix measures, the relative contribution of morbidity to the development of pressure ulcers should be investigated.

Dr. Allman described a new study funded by the National Institutes of Aging which was to be initiated in December, 1988. The study population will consist of 900 bedridden patients greater than 75 years of age. The baseline assessment will include measures of nutritional status such as zinc and vitamin levels. This study will examine the reliability of existing risk assessment tools, and utilize severity-of-illness measures in order to correlate the presence of pressure ulcers with morbidity and mortality rates. The costs related to the treatment of pressure ulcers over one year's time will also be collected for this geriatric population.

Workshop participants identified a need to conduct additional studies that compare available technologies for the treatment of pressure ulcers. These studies should include the rigorous comparison of the air-fluidized bed treatment to the low air-loss bed therapy, and comparison of the air flotation bed technology category of pressure relief devices to other devices or services which are found in the category of pressure reducing treatments. These comparative studies should apply agreed-upon measures of study population characteristics, reductions in pressure measurements, wound staging criteria, and outcome assessments. A common data bank should be established, with studies performed in a complementary and a comparable fashion. These comparisons would be helpful in determining which patients would benefit most from a particular therapy, when to shift a patient from one therapy to another, and the relative advantages and disadvantages associated with each method.

More reliable information is needed on the incidence, prevalence and outcomes of patients presenting with pressure ulcers. There appear to be biases against thorough reporting of pressure ulcers and a tendency not to rank pressure ulcers high on a list of diagnoses. Panelists around the table reported instances of fines on the order of $15,000 to $20,000 which were being levied in the state of California for reported cases of pressure ulcers in acute and extended care facilities. In his study of patients with pressure ulcers in the acute care setting, Dr. Allman found that less than one third of patients had a code for pressure ulcers among the top five diagnoses on their billing claims form. Therefore, there may be many more cases of pressure ulcers which are not captured in the current claims filing and reporting system. If these numbers could be documented, the public health significance of the problem of pressure ulcers could be underscored.
The panel and audience discussed the problems of availability and accessibility of research funds for activities related to pressure ulcer treatment. Participants noted that there was a general deficiency of funds for research on preventive care, including the problem of pressure ulcers. One proposed research activity was to examine the cost-effectiveness of prevention of pressure ulcers, which would include measures of the nursing and personnel hours, device costs, costs of recurrent sores, etc., in the calculation of costs and benefits.

It was agreed that a limited amount of funds have been available or expended for the study of pressure ulcers, their management and the technologies and devices intended for their treatment. More funds are needed in order to answer the research questions outlined thus far. It has been difficult for some researchers to find interest and financial support for their projects. The National Center for Nursing Research has funds available for research projects, but also has strict qualifications and guidelines. The National Center for Health Services Research and Health Technology Assessment is another potential source, but overall, its funds are quite limited. Instead, it appears that there is no distinct funding source for the evaluation of and improvement in the care of patients with pressure ulcers.

Many existing research studies have been funded by manufacturers. This raises a potential for bias. There is the additional problem of developing interest in and finding sponsorship for a comparative study of technologies on the part of individual manufacturers. In cases of a common good, i.e., the findings of a comparative technology assessment, it is difficult to raise funds from private sources. Participants called for greater involvement of the Health Care Financing Administration, in particular, the Medicare program and the Office of Research and Demonstration, because pressure ulcers are a significant national health problem for the elderly.

X. Panel Discussion on Regulatory Process for Coverage and Reimbursement

Frank Case, J.D.
Ruth Galten, RN
Joel E. Miller

The panel discussed the third-party payer coverage and reimbursement policies which would govern the review and appropriateness of air-flotation bed technology placed in the home setting. Mr. Case began the session with a detailed description of the Medicare Part B Insurance Program and an explanation of the key terminology. This program is commonly known as the Supplementary Medical Insurance Program, and is primarily funded by supplementary premiums paid by beneficiaries, and also by some federal funds.

The air-flotation bed technology would be considered as a Durable Medical Equipment in the Medicare Part B billing claims. Durable Medical Equipment is defined by Medicare policy as equipment that would withstand repeated use, is intended for a medical purpose, is not useful in the absence of illness or harm, and is paid for on a rental or purchase basis. There have been various interpretations given for the definition of the home setting: a dwelling, an apartment house, a relative’s home, a nursing home or other intermediate care facility.

One key term in the determination of the decision to approve payment for a service rendered a Medicare beneficiary is "medical necessity." Even when a technology or service has been formally been approved for Medicare coverage, this does not necessarily mean that it will be covered anywhere in the country or under all circumstances. Instead, the claim approval may vary by location, physician, physician specialty and type of service. Medicare carriers are independent insurance companies which serve to process Medicare claims in each state, and have the discretionary power to set individual policy determinations in some instances. This review may be based on medical reasons, but may also include the factor of treatment costs into decisions to provide or to deny payment. For example, some considerations in the decisionmaking process may
be the cost of treatment in proportion to the expected medical benefits, and the availability of less costly alternative treatments.

Another key Medicare term which is used in payment determination is "reasonableness." For Medicare Part B claims, payment is made on a reasonable charge basis, and Medicare pays an 80% proportion of the reasonable charge level. The beneficiary is liable for the remaining 20% portion, which is often covered by coinsurance. For an established rental item, carriers base the payment rate on historical charges from submitted claims found in their database, and pay 10% of the purchase price. For a new product or new product classification, there is no historical data available. Therefore, there may be more uncertainty in the payment determination for a new product, but hopefully, the resultant rate would correspond to 10% of the purchase price.

Ms. Galten described provisions of the Medicare Part A program which were relevant to the coverage of technologies in the home. In the case of air-flotation bed treatment, she noted the inconsistency which exists between Part A and Part B Policies. Conceptually, under the Medicare Part A Program, this service is already covered for institutional use, and meets the requirements of physician certification, skilled services, and medical necessity. Therefore, if it is already used and paid for in institutions under the Part A program, it should also be allowed in the home setting, given the proper guidelines for use are established.

Ms. Galten also emphasized the need to expand the focus of coverage assessment of air-flotation bed technology. Not only should the indications of pressure ulcers and wound care be studied, but also its applicability for terminally ill patients with intractable pain, burn patients, AIDS patients, bed-bound patients, severely debilitated patients, and quadriplegic patients could be assessed, thereby including the spectrum of patients who could benefit from the use of air-flotation beds. She also noted the differences in payment levels between supplies which are billed under Part A, and supplies which are billed under Part B. Under Part A, reimbursement is made for 100% of the charge, and the patient is not charged a portion as coinsurance. Under Part B, the supplier is reimbursed 80% of the charges, and the patient is liable for the remaining 20% portion of the bill. She suggested that Part A and Part B coverage and reimbursement policies be more consistent in their coverage determinations and reimbursement rate levels for home care technologies.

Mr. Miller outlined private third-party payer approaches towards the coverage of new medical technologies. The three elemental questions which are asked for each new service by the insurance company are the following: 1) Is the treatment experimental?; 2) How much should the payment be?; and 3) Is the treatment medically appropriate? The condition of medical appropriateness permits the denial of coverage in selected cases, even if the technology is not experimental.

Based on an informal survey of private insurance companies on their use of the criteria of "medical appropriateness," Mr. Miller described the following common contractual review language. A service was considered reasonable when it met the following conditions: 1) it is ordered by the physician; and 2) it is customarily and commonly recognized throughout the physician's profession as appropriate in the management of the patient's sickness, illness or injury. Another definition of the term medical necessity was a service which met the following conditions: 1) it is prescribed by a physician; 2) it is considered by a majority of the medical profession as necessary, appropriate and non-experimental care; and 3) it is not in conflict with accepted medical standards. Other analogous policies were in place for defining usual and necessary medical care, or generally accepted medical practice.

Mr. Miller also described standard review policies which are in use by third-party payers for determining coverage of a new technology. These included three critical elements: 1) medical society approval; 2) internal medical review by the company; and 3) policyholder interest and preference. The most critical factor appeared to be policyholder interest. There was a low rate of acceptance of the final Medicare coverage
decision as a key determinant in the decision to provide private insurance coverage.

The steps involved in an internal medical review process included the following: review of the clinical literature, attendance of relevant medical conferences and presentations, consultation with researchers, academicians and practitioners, and consultation with medical technology assessment organizations. Elements of a formalized coverage decision-making process included: 1) consideration of risk factors; 2) approval by medical technology assessment organizations; 3) satisfaction of the medical need criteria which are established by the hospital; 4) the medical status of the patient; and 5) alternative treatment measures which have already been pursued. In addition, the responsible physician may be contacted by the claims reviewer in order to provide additional information about the patient’s medical history, and health status. Committees have also been established within insurance companies for the purpose of assessing new medical technologies, and have included actuarial, marketing, and medical professionals.

Mr. Miller also described newer strategies which insurance companies are pursuing in order to affect the quality and costs of health care services more actively than in the past. This approach has been termed as “managed care,” which is designed to contain costs, and is composed of the following basic elements: 1) reimbursement policy, e.g., who will be paid, how will they be paid, and how much will they be paid; 2) utilization and quality of care review; and 3) coverage policy, e.g., governing services, indications, and settings of care. Increasingly, the managed care approach will rely on sophisticated and detailed clinical and financial data for specific services, instead of relying on global measures of resource use. This means that new technologies will confront more rigorous qualifications for coverage and reimbursement approval, and will require greater medical and economic documentation.

The panel discussed the documentation of pressure ulcers, different practices followed across the country, differences in categorization schemes for pressure ulcers, and the needs for and perceived difficulties in the standardization of such practices. There are classification systems that categorize ulcers into different stages or grades according to the amount of tissue destruction. It was noted that staging pressure ulcers can be difficult, because of the inaccuracies in determining the amount of tissue injury from the surface appearance of the wound. Ms. LaMantia noted that providers can disagree about current documentation and wound staging criteria, and that techniques such as infrared photography and serial color photography have also been utilized in order to characterize more objectively the depth of tissue injury.

Currently, there is no universal pressure ulcer classification. A review of the pressure ulcer literature revealed that ulcer classification systems have between three to six grades. Some systems use numbers and some use letters to denote the various categories. Consequently, there is a great deal of variance and confusion over the meaning of the various stages of pressure ulcers. For example, the Merck manual defines a different staging scheme than the one developed by the International Association for Enterostomal Therapy. These classification systems attempt to characterize the amount of tissue destruction for each pressure ulcer, but they do not provide a mechanism for denoting improvement or deterioration of the wound. In order to provide a better means of communicating the condition of the pressure ulcer, Ms. Maklebust suggested that there be subcategories of the Shea classification system. The subcategories could provide the characteristics of both the wound and
surrounding tissue, such as the presence of erythema, necrotic tissue, drainage, etc.

Panelists agreed that the classification of pressure ulcers needs to be standardized so that health care providers and researchers can communicate with each other. This would provide a basis for understanding and for referencing findings from different settings and locations. Ms. Cioshi noted that, as in other areas of patient care, greater standardization could be established for the description of the severity and specificity of wounds. Providers also desire to have a more descriptive and comprehensive classification scheme in place in order to provide a more complete assessment of the severity of the wound. Researchers need to track patients more accurately for correlation of disease characteristics with outcome.

Conversely, less sophisticated and less detailed methods of classification are needed by third-party payers. In order to establish criteria for deciding whether to accept a claim for reimbursement, third-party payers need a simple but precise system of classification, e.g., a limited grading scale of Stages I, II, III and IV. Third-party payers also need a system to help them differentiate patients requiring specialized types of therapy from patients who could be managed successfully with less sophisticated therapies. For example, Dr. Allman suggested that simple descriptors, e.g., deep, superficial, red, yellow and black, could be utilized for the purposes of reimbursement decisions. This differentiation would be based on the ability to heal and treatment requirements, because superficial wounds heal by the process of epithelialization, and deep wounds require granulation.

The disparate needs and objectives of providers, researchers and third-party payers make it difficult to agree upon a universal pressure ulcer classification scheme. One suggested option was to combine a descriptive narrative for wound assessment for use by health care providers and researchers with a simple staging assignment that is intended primarily for the use of third-party payers. Another suggestion was to maintain the general staging categories, and to expand the subclassification headings for greater understanding or description of improvement or deterioration of the wound. For example, there may be a category of Stage III wounds which also contains the subclasses A, B and C. These subheadings could denote different specific wound characteristics such as color, drainage, necrosis, infection, surrounding erythema, induration, etc. It is hoped that such a system would meet the needs of all parties interested in the problem of pressure ulcers.

There may be many patients in the acute care setting whose pressure ulcers are not identified. The problem of underreporting is thought to be linked to the stigma attached to a high institutional incidence of pressure ulcers, and fear of censure and possible fines for reporting incidences. Furthermore, the entire outpatient population is not being captured in our data monitoring and analysis system. Most patients with pressure ulcers are admitted to acute care facilities with numerous medical diagnoses, and a pressure ulcer may go unrecorded or fall as last in the listing of discharge diagnoses. This makes it difficult to collect frequency data on pressure ulcers.

In clinical practice, it was reported that nurses are using nursing diagnoses to document patient problems. Pressure ulcers are identified as "altered skin integrity" or "altered tissue integrity." If nursing diagnoses were coded into the medical record, it might be possible to collect more accurate data on pressure ulcers. Currently, health statistics are based on disease statistics. Illnesses are classified using the World Health Organization's International Classification of Diseases (ICD). Every U.S. health care agency submits statistics to a national data bank for compilation of national statistics. Recently, the American Nurses Association and the North American Nursing Diagnosis Association initiated a joint request to the World Health Organization to have nursing diagnoses included in the next revision of the ICD. This would permit the collection of international statistics on nursing diagnoses as well as medical diagnoses. This information would more closely reflect the actual incidence rate of pressure ulcers. The problems of data collection and reporting need to be addressed on a national level.
XIII. Panel Discussion of Current Clinical Decision Making and Referral Practices for Air-Flotation Bed Treatment

Richard M. Allman, M.D.
Carol Goodman, RN
G. Allen Holloway, Jr., M.D.
Holly Lidowski, RN, MSN
Sue Schindler, RN, CETN

The panel discussed current practices which are employed in the institutional setting for the ordering and selection of specialized bed treatment, the provider team responsibilities in the supervision, monitoring and delivery of primary care, and the implications for maintaining quality standards of care in the home setting. Dr. Allman reported that it appears to be common practice in his institution that when the attending physician ordered a specialized bed treatment, the bed was provided to the patient. Nurses play a key role in indicating when such a bed treatment is necessary or in recommending which type of bed treatment is most appropriate for meeting the patient’s needs. Often, a nursing specialist, such as an enterostomal therapy nurse or a rehabilitation therapy nurse, will assess the patient and then make recommendations regarding the appropriateness of application of the air-flotation bed.

Dr. Holloway described the selection and decision-making processes at his institution, which is a Level I trauma center and has a moderately sized burn care unit. Prior to the selection of specialized bed treatments, the patient is evaluated either by himself or his enterostomal therapy nurse. In this assessment, he considers all the patient’s risk factors for immobility, and for the development or progression of pressure ulcers. Low air-loss beds are automatically granted to patients admitted with extensive burns. Once on the air-flotation bed treatment, patients are evaluated on a regular biweekly basis, and are downgraded to pressure reducing devices when so indicated by their tolerance and progress in healing.

Ms. Lidowski emphasized the continuum of clinical care and treatment modalities in the assessment of the patient. She also highlighted the multidisciplinary approach to pressure ulcer management, and the cooperation and working together of a team in order to provide optimal treatment for the patient. Various health professionals are involved in the delivery of care to these patients, including physicians, nurses, nurse specialists, rehabilitation nurses, physical therapists, geriatric specialists, dieticians, etc. Expertise and attention to all aspects of wound healing are important in the care of patients receiving air-flotation bed treatment in the home setting, including education, monitoring and support of proper nutritional intake. Also, formal systems need to be developed to assign accountability for the supervision and monitoring of care by health care professionals. The component of quality assurance and accountability is important in delivery of care in the home care setting.

Ms. Schindler outlined the responsibilities for and care of patients on air-flotation bed technology in the hospital setting, which are considerations that also could be applied to the home setting. These included responsibilities for selecting the patients who would benefit from such care; determining which is the appropriate bed technology based on expertise, the patient’s requirements, and the treatment objectives; deciding the appropriate length of time for treatment; and assessing the outcome of treatment and the likely outcome if such treatment had not been instituted. Nursing care measures are a critical component of the care of these patients, including patient positioning, wound evaluation and inspection, monitoring of fluid and food intake, skin and wound care, management of any incontinence problems, monitoring of the proper functioning of the bed, including the bed pressures and temperature, and orientation and coordination of other caregivers. Ms. Schindler concluded by stating that although there are opportunities for additional research and study, we should not forget to focus upon what is known and what has been shown to be effective therapy in order to improve the management of pressure ulcers.
XIII. U.S. Congress Bipartisan Commission on Comprehensive Health Care

Robert Burke, Ph.D.

Dr. Robert Burke explained the origins and the mission of the U.S. Congress Bipartisan Commission on Comprehensive Health Care. This commission was mandated by Title IV in the Medicare Catastrophic Care Act of 1988. This Act provided for a bipartisan commission, composed of six senators, six representatives and three Presidential appointees. The Congressional members are composed of four Democratic House and two Republican House members, and four Democratic and two Republican Senate members. The Commission has a one year term, and the first meeting of the Commission has not yet been held, because of the political elections and related business.

One of the key questions which the Commission is expected to answer is about expectations for the future of the delivery and financing of health care. Specifically, the Commission is charged with the following duties: 1) to examine shortcomings in current health care delivery and financing mechanisms that limit or prevent access of all individuals in the United States to comprehensive health care; 2) to make specific recommendations to Congress respecting federal programs, policies and financing that are needed to assure the availability of the following: a) comprehensive long-term care services for the elderly and disabled; b) comprehensive health care services for the elderly and the disabled; and c) comprehensive health care for all individuals in the United States. In order to fulfill its mandate, the Commission is empowered with the ability to conduct necessary investigations and to gain access to technical assistance and information from other federal and congressional agencies.

The Commission is charged with producing two reports, the first on Comprehensive Long Term Care which is due within six months of the Commission’s first meeting, and the second on Comprehensive Health Care, which is due at the end of one year’s time. The gathering and analysis of data will be a crucial element in these efforts. Concerns about data submissions are centered on the following issues: how are they measured?, how are they standardized, if at all?, who is the party responsible for collecting such data?, and how reliable and valid are these data? Dr. Burke concluded by stating that there is a valuable opportunity open to the providers represented here at the workshop to submit information and findings to the Commission that are related to the clinical problem and management of pressure ulcers.
GLOSSARY OF TERMS

SOURCE: International Association for Enterostomal Therapy, Standards of Care: Dermal Wounds: Pressure Sores

Decubitus A misnomer for a pressure sore.

Dermis The inner layer of skin in which hair follicles and sweat glands originate; involved in Grade II-IV pressure sores.

Epidermis The outer cellular layer of skin.

Eschar Thick, leathery necrotic tissue; devitalized tissue.

Full-Thickness Tissue destruction extending through the dermis to involve the subcutaneous layer and possibly muscle/bone.

Granulation The formation or growth of small blood vessels and connective tissue in a full thickness wound.

Ischemia A deficiency of blood due to functional constriction or obstruction of a blood vessel to a part.

Necrotic Dead; avascular.

Partial-Thickness Loss of epidermis and possible partial loss of dermis.

Pressure Reduction Device Mattress/pad which reduces pressure as compared to standard hospital mattress/chair surface but does not keep interface pressure consistently below capillary closing pressure (e.g., alternating pressure pads, water mattresses, gel pads, air-support mattresses, high density foam).

Pressure Relief Device Device which consistently reduces interface pressure below capillary closing pressure (e.g., air fluidized therapy).

Pressure Sore or Pressure Ulcer An area of localized tissue damage caused by ischemia due to pressure.

Shear Trauma caused by tissue layers sliding against each other; results in disruption or angulation of blood vessels.

Sinus Tract A course or pathway which can extend in any direction from the wound surface; results in dead space with potential for abscess formation.

Undermine Tissue destruction underlying intact skin along wound margins.

Wound Base Uppermost viable tissue layer of wound; may be covered with slough or eschar.

Wound Margin Rim or border of wound.

Wound Repair Healing process. Partial thickness involves epithelialization; full-thickness involves contraction, granulation, and epithelialization.
SELECTED BIBLIOGRAPHY


Griffith, J. and Christensen, P.: Nursing process: Application of theories, frameworks, and models (pp. 4-5), Published by Mosby Co., St. Louis.


FDA MEDICAL DEVICE CLASSIFICATION

The following describes the Food and Drug Administration's generic categories of air-fluidized beds and powered flotation therapy beds:

Classification Name: Air Fluidized Bed
Classification Code: 890.5160, Physical Medicine
Classification Category: Class II

Classification Definition: "An air-fluidized bed is a device employing the circulation of filtered air through ceramic spherules (small, round ceramic objects) that is intended for medical purposes to treat or prevent bedsores, to treat severe or extensive burns, or to aid circulation."

Classification Name: Powered Flotation Therapy Bed
Classification Code: 890.5170, Physical Medicine
Classification Category: Class II

Classification Definition: "A powered flotation therapy bed is a device that is equipped with a mattress that contains a large volume of constantly moving water, air, mud, or sand. It is intended for medical purposes to treat or prevent bedsores, to treat severe or extensive burns, or to aid circulation."

Classification Name: Manual Patient Rotation Bed
Classification Code: 890.5180, Physical Medicine
Classification Category: Class I

Classification Definition: "A manual patient rotation bed is a device that turns a patient who is restricted to a reclining position. It is intended for medical purposes to treat or prevent bedsores, to treat severe or extensive burns, or to aid circulation."
Classification Name: Powered Patient Rotation Bed

Classification Code: 890.5225, Physical Medicine

Classification Category: Class II

Classification Definition: "A powered patient rotation bed is a device that turns a patient who is restricted to a reclining position. It is intended for medical purposes to treat or prevent bedsores, to treat severe or extensive burns, urinary tract blockage, and to aid circulation."

Classification Name: Nonpowered Flotation Therapy Mattress

Classification Code: 880.5150, General Hospital

Classification Category: Class I

Classification Definition: "A nonpowered flotation therapy mattress is a mattress intended for medical purposes which contains air, fluid, or other materials that have a functionally equivalent effect of supporting a patient and avoiding excess pressure on local body areas. The device is intended to treat or prevent decubitus ulcers (bed sores)."

Classification Name: Alternating Pressure Air Flotation Mattress

Classification Code: 880.5550, General Hospital

Classification Category: Class II

Classification Definition: "An alternating pressure air flotation mattress is a mattress intended for medical purposes which consists of a mattress with multiple air cells that can be filled and emptied in an alternating pattern by an associated control unit to provide regular, frequent, and automatic changes in the distribution of body pressure. The device is intended to treat or prevent decubitus ulcers (bed sores)."
MEDICARE DURABLE MEDICAL EQUIPMENT

The following describes Medicare's screening list of and coverage guidelines for medical technologies related to the treatment and prevention of pressure ulcers in the home setting:

Air-Fluidized Bed

- (see Bead Bed)

Alternating Pressure Pads and Mattresses and Lambs Wool Pads

- covered if patient has, or highly susceptible to, decubitus ulcers; and a patients physician has specified that he will be supervising its use in connection with his course of treatment.

Bead Bed

- deny--institutional equipment; inappropriate for home use

DePuy Flote Bed

- (see Alternating Pressure Pads and Mattresses)

DePuy Flotation Mattress

- (see Alternating Pressure Pads and Mattresses)

Gel Flotation Pads and Mattresses

- (see Alternating Pressure Pads and Mattresses)

Grant Alternating Pads and Mattresses

- (see Alternating Pressure Pads and Mattresses)
Lambs Wool Pads

- covered under the same condition as alternating pressure pad or mattress.

Medic-Ease Mattress

- covered under the same condition as alternating pressure pad or mattress. Base reimbursement on less expensive item if that satisfies patient's need.

Pressure-Eze-Pad

- (see Alternating Pressure Pads and Mattresses)

Oscillating Bed

- deny--institutional equipment; inappropriate for home use

Stryker Flotation Pads and Mattresses

- (see Alternating Pressure Pads and Mattresses)

Vasculaider Bed

- deny (see Oscillating Beds)

Vasosiccillating Bed

- deny (see Oscillating Beds)

Water and Pressure Pads and Mattresses

- (see Alternating Pressure Pads and Mattresses)
MISSION

The Medical Technology and Practice Patterns Institute, Inc. (MTPI) conducts analytic research on new and emerging medical technologies and, in particular, their implications for national policy. A key element in these efforts is the joining of public and private resources to address the issues under consideration. The general objective of the Institute is to provide both public and private policy decision-making processes with the most current information available regarding adoption and use of new medical technologies.

The Institute is particularly concerned with issues regarding the introduction of new and emerging major medical technologies into the health care delivery system. The rapidity and proliferation of technological advances in medicine often result in decision-makers not being prepared to assess new technologies in a formal and thorough manner. Thus, there is an important need for accurate, up-to-date information concerning costs and other aspects of new medical technologies. The Institute collects, analyzes and disperses information critical to the rational management of new and emerging medical technologies. The Institute makes every effort to make its findings available to the Congress, the Executive Branch and the private sector in a timely and useful fashion.

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The Institute is an independent non-profit corporation. Its staff and associates are composed of senior and junior professionals from varied disciplines and experiences. The composition of the staff and associates is designed to accomplish in-depth analytical approaches — biomedical, legal, economic and administrative, as well as interactive collaborative approaches — so as to provide a well-rounded, objective investigation of any given problem.

The Institute is also able to draw upon its collaborative ties and working relationships with individuals and resources of affiliated institutions. Individuals from outside the Institute, whose disciplinary backgrounds and expertise correspond to the interests and objectives of the Institute or who contribute to the Institute’s work, are designated as Associates to the Institute.

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The Institute manages three major research activities:

1. **National Health Services and Practice Patterns Survey.** Utilizing the National Health Services and Practice Patterns Survey, the Institute performs independent surveys and other forms of health services research and analysis of selected important national policy questions regarding new and emerging medical technology. In many cases, issues chosen for study demand the application of specialized knowledge from several disciplines. The Institute serves as a catalyst to focus the expertise of public and private organizations on issues such as costs and quality of health care delivery, coverage and reimbursement policies, access to care and regulation.

2. **The Medical Technology Forum.** The Medical Technology Forum includes sponsorship of workshops, conferences and seminars on selected topics. In each case, these are designed to convene particularly knowledgeable individuals who possess special understanding of the significance and implications of costs and quality of health care delivery, coverage and reimbursement policies, access to care, regulation and other issues. These meetings serve as objective forums for the variety of points of view and diverse factions of the health care delivery system which typically characterize the important, wide-reaching implications of technology for public policy issues.

3. **Special Functions: Hospital Stay Charge Profile.** Finally, the Institute undertakes special functions such as analysis of public and private health care costs and service utilization data bases (e.g., Medicare’s inpatient and outpatient claims files, the National Hospital Discharge Survey, the American Hospital Association Survey, etc.). Data collected from hospital discharge abstracts of medical records and charge data provide insight and advance understanding of changes in case mix-adjusted pricing and utilization. HSCP is a useful information and evaluation tool for hospital coalitions, government agencies, health care providers and individual hospitals.

(Over)
4. Physician Charge Profile. The Physician Charge Profile (PCP) is a service designed to provide analysis of (1) current demand for physician services, (2) resources consumed during the episode of care, and (3) practice pattern information related to the care given Medicare beneficiaries. PCP is a helpful analytic instrument to segment and study specific patient subgroups, identify specific services in need of productivity gains and predict future patient care needs.

5. Hospital Mortality Rate Profile. The Hospital Mortality Rate Profile (HMMP) produces information that links mortality statistics with institutional characteristics, and categorizes similarly-situated institutions for comparison. Analyzes are tailored to fit the specific needs of the hospital on a confidential basis. The Profile is useful to compare the case volume and performance of the hospital to other institutions and to evaluate concerns related to quality of care.

TECHNOLOGIES UNDER STUDY

Among the many technologies under study, the following are in an advanced stage of analysis:

- Magnetic Resonance Imaging (In pt. & Out pt.)
- Percutaneous Transluminal Coronary Angioplasty
- Extracorporeal Shockwave Lithotripsy (In pt. & Out pt.)
- Percutaneous Lithotripsy
- Endocardial Electrical Stimulation
- Heart Transplantation
- Implantable Cardiac Defibrillators
- Ambulatory Blood Pressure Monitoring
- Liver Transplantation
- TPA Thrombolytic Therapy
- Inpatient Dialysis Treatment for End-Stage Renal Disease
- Bone Marrow Transplantation
- Therapeutic Photopheresis

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FINANCIAL SUPPORT

The Institute is a non-profit corporation that derives its financial support from a wide range of entities representing the spectrum of commitments and interests concerned with national health policy regarding the introduction, diffusion and appropriate use of new medical technology, and other health-related issues.

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AIR POLLUTION BED TECHNOLOGY IN THE HOME SETTING
Public Policy Implications Related to Use of
Workshop Summary Report